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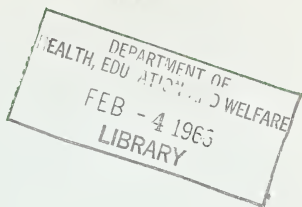
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HEALTH INSURANCE FOR THE AGED

CONDITIONS OF PARTICIPATION FOR HOSPITALS

U.S. Bureau of Health Insurance



U.S. DEPARTMENT OF
HEALTH, EDUCATION, AND WELFARE
SOCIAL SECURITY ADMINISTRATION

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CONDITIONS OF PARTICIPATION FOR HOSPITALS

Introduction

In order to participate as a hospital in the health insurance program for the aged, an institution must be a "hospital" within the meaning of section 1861(e) of the Social Security Act. This section of the law states a number of specific requirements to be met by participating hospitals, and authorizes the Secretary of Health, Education, and Welfare to prescribe other requirements considered necessary in the interest of health and safety of beneficiaries. The requirements included in the statute and the additional health and safety requirements to be prescribed by the Secretary are incorporated into the Conditions of Participation for Hospitals. It should be noted in using this material that general hospitals which are accredited by the Joint Commission on Accreditation of Hospitals will be directly concerned only with the requirement for utilization review since they are deemed to meet all of the other conditions of participation.

The Conditions of Participation for Hospitals and related policies, as set forth herein, will be reflected in regulations of the Department of Health, Education, and Welfare. Meanwhile, the Social Security Administration is making the conditions available to institutions as well as to State agencies and other organizations involved in the process of establishing the qualifications of institutions in order that interested institutions may apply for a determination of their eligibility to participate in the health insurance program. The law makes provision for the designation of State health agencies, or other State agencies, to assist the Department in determining whether the conditions of participation have been met. The designated State agencies will certify to the Department of Health, Education, and Welfare institutions which meet the conditions and will provide consultation to institutions to assist them to qualify. A hospital which meets all of the specific statutory requirements and is found to be in substantial compliance with the additional conditions prescribed in regulations may, if it so desires, agree to become a participating hospital.

The conditions of participation have been developed in accordance with the requirements, authorizations and limitations in the law.¹ Concurrently with the release of these materials to interested individuals, organizations and agencies, the Department of Health, Education, and Welfare will proceed with the necessary action to establish conforming regulations. The official Notice of Proposed Rule Making and of the opportunity for submission of data, comments, and arguments relating to the proposed regulations is being provided in accordance with the regular procedure of publication in the Federal Register.

In the preparation of the conditions of participation, there has been extensive discussion and consultation with organizations and experts in the field of hospital and medical care. Groups consulted included representatives of State health and welfare departments, the American Hospital Association, American Medical Association, Joint Commission on Accreditation of Hospitals, American Nurses Association, American Osteopathic Association, among others. The conditions of participation have also been reviewed and endorsed by the Health Insurance Benefits Advisory Council, the statutory body established for the purpose of advising the Secretary on matters of general policy in the administration of this program and in the formulation of applicable regulations.

Hospitals Accredited by the Joint Commission on Accreditation of Hospitals

Hospitals currently accredited by the JCAH will be deemed to meet all of the conditions of participation, except the requirement for utilization review and, in the case of tuberculosis and psychiatric hospitals, the additional staffing and medical records requirements considered necessary for the provision of intensive care. Consequently, a JCAH-approved general hospital will be able to establish eligibility to participate by furnishing adequate evidence that it has an effective utilization review plan. Ordinarily, a written description of the

higher requirements on institutions as a condition for the purchase of services under a State plan approved under title I, XVI, or XIX of the Social Security Act, the Secretary is required to impose like requirements as a condition to the payment for services in such institutions in that State or subdivision.

¹ The law provides that the Secretary, in general, may not establish, by regulation, requirements for participating hospitals that are higher than the comparable requirements prescribed for accreditation by the Joint Commission on Accreditation of Hospitals. He may, however, at the request of a State, approve higher health and safety requirements for that State; and where a State or political subdivision imposes

plan and a certification by the hospital that the plan is either currently in effect or that it will be in effect on July 1, 1966, will constitute sufficient evidence to support a finding that the utilization review plan of such hospital is or is not in conformity with statutory requirements for such a plan. Further information on the requirements for utilization review will be found on pages 39 of this pamphlet. In addition, the appendix contains samples of forms and instructions which will be made available by State agencies to institutions for their use in submitting the necessary information.

Conditions of Participation for Hospitals Which Are Not Accredited

The conditions of participation are modeled after, and are no higher than, the requirements for accreditation of the JCAH. The JCAH and its sponsors, the American College of Physicians, the American College of Surgeons, the American Hospital Association, and the American Medical Association, have for many years been engaged in a program directed toward the attainment of hospital care meeting professional standards. The JCAH establishes and publishes minimum standards which hospitals must meet in order to become accredited and urges them to exceed those minimum requirements.

In establishing the requirements for participation by hospitals, it is clear that Congress intended that the health insurance for the aged program should not support substandard institutional care. The Report of the Committee on Ways and Means of the House of Representatives in explaining this action states at page 25:

These conditions for participation are included to provide assurance that participating institutions are safe, that they have facilities and organization necessary for the provision of adequate care, and that they exercise their responsibility to discourage improper and unnecessary utilization of their services and facilities. The inclusion of these conditions is designed to support the efforts of the various professional accrediting organizations sponsored by the medical and hospital associations, health insurance plans, and other interested parties to improve the quality of care in hospitals. To allow payments to institutions for services of lower quality than are now generally acceptable might reduce the incentive for establishing high quality institutions or for maintaining high standards where they now exist. (Identical language appears at pp. 28-29 of the Report of the Senate Committee on Finance.)

For an institution to be eligible for participation in the program, it must meet the specific statutory requirements in section 1861(e), as well as the additional conditions established in the interest of health and safety

which are essential to the maintenance of quality of care and the adequacy of the services and facilities which the institution provides. It will not be unusual for hospitals to differ in the manner in which these conditions will be met. Variations in the type and size of hospitals and the nature and scope of services offered will be reflected in differences in the details of organization, staffing and facilities. *However, the test will be whether there is substantial compliance with each of the conditions.*

As a basis for a determination as to whether or not there is substantial compliance with the prescribed conditions in the case of any particular hospital, a series of standards, almost all interpreted by explanatory factors, are listed under each condition. These standards represent a broad range and variety of activities which hospitals may undertake or be pursuing in order to carry out the functions embodied in the conditions. Reference to these standards will enable the State agency surveying a hospital to document the activities of the hospital, to establish the nature and extent of the hospital's deficiencies, if any, with respect to any particular function, and to assess the hospital's need for improvement in relation to the prescribed conditions. In substance, the application of the standards, together with the explanatory factors, will indicate the extent and degree to which a hospital is complying with each condition.

Procedures for Establishing Eligibility To Participate

The Health Insurance for the Aged Act provides that the services of State agencies, operating under agreements with the Department, will be used by the Department in determining whether institutions meet the conditions of participation. Pursuant to these agreements, State agencies will certify to the Department hospitals which are found to be in substantial compliance with the conditions. Such certifications shall include findings as to whether the facilities and services of the hospital substantially meet the conditions. The Department, on the basis of such certification from the State agency, will determine whether or not an institution is a hospital eligible to participate in the health insurance program as a provider of services.

The decisions of the State agency represent recommendations to the Secretary. Notice of determination of eligibility or noneligibility made by the Department on the basis of a State agency decision will be sent to the institution concerned by the Social Security Administration after such review and professional consultation with the Public Health Service as may be required. If it is determined that the institution does not comply with the conditions of participation, the institution has

a right to appeal the determination and request a hearing. If the final decision which an institution receives after an appeal is unfavorable, the institution may request judicial review by the Federal courts.

The appendix of this pamphlet contains samples of the forms and instructions which will be made available by State agencies to hospitals and which will be used to initiate the process of establishing eligibility. In addition to utilizing information available in licensure or other files, State agencies will conduct such surveys as may be necessary to determine the degree to which the conditions are met. A hospital may obtain further information or assistance from the designated State agency or from the regional representative, Bureau of Health Insurance, Social Security Administration. The address of the designated State agency or the regional office can be secured from any district office of the Social Security Administration.

Principles for the Evaluation of Hospitals to Determine Whether They Are in Substantial Compliance With the Conditions of Participation²

Hospitals will be considered in substantial compliance with the conditions of participation upon acceptance by the Secretary of findings, adequately documented and certified to by the State agency, showing that:

- A. The hospital is:
 1. Accredited by the JCAH, and
 2. Has established a utilization review plan meeting the statutory requirements of section 1861 (k) and such plan is in effect or will be put into effect no later than the first day a hospital expects to become a participating provider of services (ordinarily July 1, 1966), or
- B. The hospital meets the specific statutory requirements of section 1861 (e) and is found to be operating in accordance with all conditions of participation with no significant deficiencies, or
- C. The hospital meets the specific statutory requirements of section 1861 (e) but is found to have deficiencies with respect to one or more conditions of participation which:
 1. It is making reasonable plans and efforts to correct, and
 2. Notwithstanding the deficiencies, is rendering adequate care and without hazard to the health and safety of individuals being served, taking into account special procedures or precautionary measures which have been or are being instituted.

Time Limitations on Certifications of Substantial Compliance

All initial certifications by the State agency to the effect that a hospital is in substantial compliance with the conditions of participation will be for a period of 2 years, beginning with July 1, 1966, or, if later, with the date on which the hospital is first found to be in substantial compliance with the conditions. State agencies may visit or resurvey institutions where necessary to ascertain continued compliance or to accommodate to periodic or cyclical survey programs. A State finding and certification to the Secretary that an institution is no longer in compliance (see next topic) may occur within a 2-year or subsequent period of certification and will thereby terminate the State's certification as to compliance.

If a hospital is certified by the State agency as in substantial compliance under the provisions of paragraph C., above, the following information will be incorporated into the finding and into a notice of eligibility to the hospital:

- A. A statement of the deficiencies which were found, and
- B. A description of progress which has been made and further action which is being taken to remove the deficiencies, and
- C. A scheduled time for a resurvey of the institution to be conducted not later than the 18th month (or earlier, depending on the nature of the deficiencies) of the period of certification.

Certifications of Noncompliance

The State agency will certify that an institution is not in compliance with the conditions of participation or, where a determination of eligibility has been made, that an institution is no longer in compliance where:

- A. The institution is not in compliance with one or more of the statutory requirements of section 1861 (e), or
- B. The institution has deficiencies of such character as to seriously limit the capacity of the institution to render adequate care or to place health and safety of individuals in jeopardy, and consultation to the institution has demonstrated that there is no early prospect of such significant improvement as to establish substantial compliance as of a later beginning date, or
- C. After a previous period or part thereof for which the institution was certified with a finding of significant deficiencies, there is a lack of progress toward a removal of deficiencies which the State agency finds are adverse to the health and safety of individuals being served.

²For exception and special rules applying to tuberculosis and psychiatric hospitals, see pages 43-54.

If, on the basis of a State agency certification, it is determined by the Department of Health, Education, and Welfare that the hospital no longer substantially meets the conditions of participation, the agreement under which the hospital participates in the program may be terminated after reasonable notice and opportunity for a hearing.

Criteria for Determining Substantial Compliance

Findings made by a State agency as to whether a hospital is in substantial compliance with the conditions of participation require a thorough evaluation of the degree to which operation of a hospital demonstrates adequate performance of the functions which are embodied in the conditions. The State evaluation will take into consideration:

- A. The degree to which each standard, as well as the total set of standards relating to a condition of participation, are met;
- B. When there is a deficiency in meeting a standard, whether the deficiency is one concerning the statutory requirements which must be met by all hospitals (section 1861(e), Public Law 89-97, see appendix);
- C. Whether the deficiency creates a hazard to health and safety;
- D. Whether the hospital is making reasonable plans and efforts to correct the deficiency within a reasonable period.

Documentation of Findings

The findings of the State agency with respect to each of the conditions of participation should be adequately documented. Where the State agency certification to the Department of Health, Education, and Welfare is that an institution is not in compliance with the conditions of participation, such documentation should include a report of all consultation which has been undertaken in an effort to assist the institution to comply with the conditions, a report of the institution's responses with respect to the consultation, and the State

agency's assessment of the prospects for such improvements as to enable the institution to achieve substantial compliance with the conditions.

Authorization for Special Certification in Areas Where Necessary to Providing Access to Hospital Care

Where, by reason of factors such as isolated location or absence of sufficient facilities in an area, the denial of eligibility of an institution to participate would seriously limit the access of beneficiaries to participating hospitals, an institution may, upon recommendation by the State agency, be approved by the Department of Health, Education, and Welfare as a provider of services. Such approvals will be granted only where there are no deficiencies of such character and seriousness as to place health and safety of individuals in jeopardy. An institution receiving this special approval shall furnish information showing the extent to which it is making the best use of its resources to improve its quality of care. Resurveys of such institutions will be made at least annually.

Each case will have to be decided on its individual merits; and while the degree and extent of compliance will vary, the institution must, as a minimum, meet all of the statutory conditions in section 1861(e) (1)-(7), in addition to meeting such other requirements as the Secretary finds necessary under section 1861(e) (8).

Provisions of Emergency Services by Nonparticipating Hospitals

An institution which has not been determined by the Department of Health, Education, and Welfare as being in compliance with all of the conditions, and which is not accepted as a participating hospital, may, nevertheless, be paid under the program for emergency services furnished, provided it meets requirements established pursuant to section 1861(e) (1), (2), (3), (4), (5), and (7) of the Social Security Act as amended. Program policies and definitions applying to emergency services are being prepared and will be issued later.

Condition of Participation

I. COMPLIANCE WITH STATE AND LOCAL LAWS

THE HOSPITAL IS IN CONFORMITY WITH ALL APPLICABLE STATE AND LOCAL LAWS.

Standard A

The hospital, in any State in which State or applicable local law provides for the licensing of hospitals, (1) licensed pursuant to such law, or (2) is approved, by the agency of the State or locality responsible for licensing hospitals, as meeting the standards established for such licensing.

Standard B

Staff of the hospital is licensed or registered in accordance with applicable laws.

Standard C

The hospital is in conformity with laws relating to fire and safety, to communicable and reportable diseases, to post-mortem examinations, and to other relevant matters.



Condition of Participation

II. GOVERNING BODY

THE HOSPITAL HAS AN EFFECTIVE GOVERNING BODY* LEGALLY RESPONSIBLE FOR THE CONDUCT OF THE HOSPITAL AS AN INSTITUTION.

Standard A

The governing body has adopted bylaws in accordance with legal requirements.

Factor 1. The bylaws are in writing and available to all members of the governing body.

Factor 2. The bylaws:

(i) Stipulate the basis upon which members are selected, their term of office, and their duties and requirements; (ii) Specify to whom responsibilities for operation and maintenance of the hospital, including evaluation of hospital practices, may be delegated; and the methods established by the governing body for holding such individuals responsible; (iii) Provide for the designation of necessary officers, their terms of office and their duties, and for the organization of the governing body into essential committees; (iv) Specify the frequency with which meetings will be held; (v) Provide for the appointment of members of the medical staff; and (vi) Provide mechanisms for the formal approval of the organization, bylaws, rules and regulations of the medical staff and its departments in the hospital.

Standard B

The governing body meets at regular, stated intervals.

Factor 1. Meetings are held frequently enough for the governing body to carry on necessary planning for growth and development and to evaluate the conduct of the hospital, including the care and treatment of patients, the control, conservation and utilization of physical and financial assets, and the procurement and direction of personnel.

Factor 2. Minutes of meetings reflect pertinent business conducted, and are regularly distributed to members of the governing body.

*If a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital carry out the functions herein pertaining to the governing body.

Standard C

The governing body appoints committees. There should be an Executive Committee and others as indicated for special purposes.

Factor 1. The number and types of committees appointed are consistent with the size and scope of activities of the hospital.

Factor 2. An Executive Committee, or the governing body as a whole, coordinates the activities and general policies of the various hospital departments and special committees established by the governing body.

Factor 3. Written minutes or reports, which reflect business conducted by the Executive Committee, are maintained for review and analysis by the governing body.

Factor 4. Other committees, including finance, joint conference, and building and maintenance, function in a manner consistent with their duties as assigned by the governing body and maintain written minutes or reports which reflect the enactment of such duties. If such other committees are not appointed, a member or members of the governing body assume those duties normally assigned to such committees.

Standard D

The governing body has established a formal means of liaison with the medical staff by a joint conference committee or other appropriate mechanism.

Factor 1. A direct and effective method of communication with the medical staff is established on a formal, regular basis, and is documented in written minutes or reports which are distributed to designated members of the governing body and active medical staff.

Factor 2. Such effective liaison is a responsibility of the Joint Conference Committee, the Executive Committee, or designated members of the governing body.

Standard E

The governing body appoints members of the medical staff.

Factor 1. A formal procedure is established, governed by written rules and regulations, covering the application for medical staff membership and the method of processing applications.

Factor 2. The procedure related to the submission and processing of applications involves the administrator, credentials committee of the medical staff or its counterpart, and the governing body, all functioning on a regular basis.

Factor 3. Selection of physicians and definition of their medical privileges, both for new appointments and re-appointments, are based on written, defined criteria.

Factor 4. Actions taken on applications for medical staff appointments by the governing body are put in writing and retained.

Factor 5. Written notification of applicants is made by either the governing body or its designated representative.

Factor 6. Applicants selected for medical staff appointment sign an agreement to abide by the rules, regulations, and bylaws of the hospital.

Factor 7. There is a procedure for appeal and hearing by the governing body or other designated committee if the applicant or medical staff feels the decision is unfair or wrong.

Standard F

The governing body appoints a qualified hospital administrator.*

Factor 1. The administrator has had actual experience of a suitable kind, nature and duration in hospital administration.

Factor 2. Preferably, the administrator has had formal training in a graduate program in hospital administration approved by the Association of University Programs in Hospital Administration.

Standard G

The administrator acts as the executive officer of the governing body, is responsible for the management of the hospital, and provides liaison among the governing body, medical staff, nursing staff, and other departments of the hospital.

Factor 1. In discharging his duties, the administrator keeps the governing body fully informed of the conduct

*The term "hospital administrator" is used to refer to the chief executive officer, whatever his title.

of the hospital through annual, monthly, or other written reports and by attendance at meetings of the governing body.

Factor 2. The administrator organizes the day-to-day functions of the hospital through appropriate departmentalization and delegation of duties.

Factor 3. The administrator establishes formal means of accountability on the part of subordinates to whom he has assigned duties.

Factor 4. To maintain sufficient liaison between the governing body, medical and nursing staffs and other departments, the administrator holds interdepartmental and departmental meetings, where appropriate, attends or is represented at such meetings on a regular basis, and reports to such departments as well as the governing body the pertinent activities of the hospital.

Factor 5. The administrator has sufficient freedom from other responsibilities to permit adequate attention to the management and administration of the hospital.

Standard H

The governing body is responsible for establishing a policy which requires that every patient must be under the care of a physician.

Factor 1. Patients are admitted to the hospital only on the recommendation of a physician.

Factor 2. A member of the house staff or other physician is on duty or on call at all times and available within 15 to 20 minutes at the most.

Standard I

The governing body is responsible for providing a physical plant equipped and staffed to maintain the needed facilities and services for patients.

Factor 1. The governing body receives periodic written reports from appropriate intramural and extramural sources about the adequacy of the physical plant, equipment and personnel, as well as any deficiencies.

Factor 2. A member, members, or committee of the governing body is assigned primary responsibility for this aspect in the conduct of the hospital.

Factor 3. In order to provide a suitable physical plant which is well-equipped and staffed, the governing body is responsible for raising funds or otherwise arranging for the availability of funds, adopting a budget for the institution, and approving schedules of charges.

Condition of Participation

III. PHYSICAL ENVIRONMENT

THE BUILDINGS OF THE HOSPITAL ARE CONSTRUCTED, ARRANGED, AND MAINTAINED TO INSURE THE SAFETY OF THE PATIENT, AND PROVIDE FACILITIES FOR DIAGNOSIS AND TREATMENT AND FOR SPECIAL HOSPITAL SERVICES APPROPRIATE TO THE NEEDS OF THE COMMUNITY.

Standard A

The buildings of the hospital are solidly constructed with adequate space and safeguards for each patient.

Factor 1. The physical facility has current approvals following inspection by appropriate State and/or local authorities.

Factor 2. The condition of the physical plant and the over-all hospital environment are developed and maintained in such a manner that the safety and well-being of patients are assured.

Factor 3. The physical plant provides:

(i) Facilities for the physical separation of all isolation patients, particularly those with communicable diseases, and facilities for hand washing and for carrying out good medical and nursing isolation techniques; (ii) Proper facilities for handling contaminated linens; (iii) Adequate floor space per bed; in the absence of State or local requirements regarding space per bed, there is at least one hundred square feet of floor area per bed in a private room and eighty square feet per bed in multiple patient rooms; (iv) Facilities for emergency power and lighting in at least the operating, recovery, intensive care, and emergency rooms and stairwells; in all other areas not serviced by the emergency supply source, battery lamps and flashlights are available; and (v) Facilities for emergency gas and water supply.

Factor 4. There is regular inspection and cleaning of air intake sources, screens, and filters, with special attention given to "high risk" areas.

Factor 5. Proper facilities are maintained and techniques used for incineration of infectious wastes, as well as sanitary disposal of all other wastes.

Factor 6. Kitchens and dishwashing facilities located outside the dietary department comply with the standards specified for the dietary department.

Factor 7. Corridors and passageways are free of obstacles.

Factor 8. A person is designated responsible for services and for the establishment of practices and procedures in each of the following areas—plant maintenance, laundry operations, and the supervision and training of general housekeeping personnel.

Standard B

The hospital provides fire protection by the elimination of fire hazards; the installation of necessary safeguards such as extinguishers, sprinkling devices, and fire barriers to insure rapid and effective fire control; and the adoption of written fire control plans rehearsed three times a year by key personnel.

Factor 1. The hospital has:

(i) Written evidence of regular inspection and approval by State or local fire control agencies; (ii) Fire-resistant buildings, and equipment as close to fire-proof as possible; (iii) Stairwells kept closed by fire doors or equipped with unimpaired automatic closing devices; (iv) Annual check of fire extinguishers for type, replacement, and renewal dates; (v) Sprinkler systems at least for trash and laundry chutes, paint and carpenter shops, and most storage areas, and fire detection equipment for bulk storage areas; (vi) Conductive floors with the required equipment and ungrounded electrical circuits in areas subject to explosion hazards; (vii) Proper routine storage and prompt disposal of trash; (viii) "No Smoking" signs prominently displayed, where appropriate, with rules governing the ban on smoking in designated areas of the hospital enforced and obeyed by all personnel; and (ix) Fire regulations prominently posted and all fire codes rigidly observed and carried out.

Factor 2. Written fire control plans contain provisions for prompt notification of all fires; extinguishing fires;

protection of patients, personnel, and guests; evacuation; and cooperation with fire fighting authorities.

Factor 3. There are rigidly enforced written rules and regulations governing proper routine methods of handling and storing explosive agents, particularly in operating rooms and laboratories, and governing the provision of oxygen therapy.

Standard C

The hospital provides a sanitary environment to avoid sources and transmission of infections.

Factor 1. An infection committee, composed of members of the medical and nursing staffs and administration, is established and responsible for investigating, controlling, and preventing infections in the hospital. Its responsibilities include:

(i) The establishment of written infection control measures; and (ii) The establishment of techniques and systems for discovering and reporting infections in the hospital.

Factor 2. Written procedures govern the use of aseptic techniques and procedures in all areas of the hospital.

Factor 3. To keep infections at a minimum, such procedures and techniques are regularly reviewed by the infection committee, particularly those concerning food handling, laundry practices, disposal of environmental and patient wastes, traffic control and visiting rules in high risk areas, sources of air pollution, and routine culturing of autoclaves and sterilizers.

Factor 4. There is a method of control used in relation to the sterilization of supplies and water, and a written policy requiring sterile supplies to be reprocessed at specified time periods.

Factor 5. Formal provisions are made to educate and orient all appropriate personnel in the practice of aseptic techniques such as handwashing and scrubbing practices, proper grooming, masking and dressing care techniques, disinfecting and sterilizing techniques, and the handling and storage of patient care equipment and supplies.

Factor 6. There are measures which control the indiscriminate use of preventive antibiotics in the absence of infection, and the use of antibiotics in the presence of infection is based on necessary cultures and sensitivity tests.

Factor 7. Continuing education is provided to all hospital personnel on the cause, effect, transmission, prevention, and elimination of infections.

Factor 8. A continuous process is enforced for inspection and reporting of any hospital employee with an infection who may be in contact with patients, their food or laundry.

Standard D

The hospital provides adequate diagnostic and therapeutic facilities.

Factor 1. Facilities are located for the convenience and safety of patients.

Factor 2. Facilities are available which allow all routine preadmission, admission and discharge procedures to be done as prescribed by the medical staff in bylaws, rules and regulations of the hospital.

Factor 3. Diagnostic and therapeutic facilities, supplies, and equipment permit an acceptable level of patient care to be provided by the medical and nursing staffs.

Factor 4. The extent and complexity of such facilities are determined by the services that the hospital attempts to offer.

Condition of Participation

IV. MEDICAL STAFF

THE HOSPITAL HAS A MEDICAL STAFF ORGANIZED UNDER BYLAWS APPROVED BY THE GOVERNING BODY, AND RESPONSIBLE TO THE GOVERNING BODY OF THE HOSPITAL FOR THE QUALITY OF ALL MEDICAL CARE PROVIDED PATIENTS IN THE HOSPITAL AND FOR THE ETHICAL AND PROFESSIONAL PRACTICES OF ITS MEMBERS.

Standard A

The medical staff is responsible for support of medical staff and hospital policies.

Factor 1. Medical staff members participate on various staff committees. Committee records verify that committee meetings are attended by the majority of committee members.

Factor 2. There are prescribed enforced disciplinary procedures for infraction of hospital and medical policies.

Standard B

The medical staff attempts to secure autopsies in all cases of unusual deaths and of medical-legal and educational interest. It is recommended that a minimum of 20 percent of all terminal cases be autopsied.

Factor 1. The hospital has an autopsy rate consistent with the needs of its ongoing staff education program.

Factor 2. Autopsy reports are distributed to the attending physician and become a part of the patient's record. Whenever possible, they are utilized in conference.

Factor 3. The autopsy is performed by a pathologist or physician versed in autopsy procedure and protocol.

Standard C

The medical staff has established policies concerning the holding of consultations.

- The status of consultant is determined by the medical staff on the basis of an individual's training, experience, and competence. A person selected as a consultant is well qualified to give an opinion in the field in which his opinion is sought.
- Except in an emergency, consultations with another qualified physician are held in all cases in which, according to the judgment of the

attending physician: (1) the patient is not a good medical or surgical risk, (2) the diagnosis is obscure, (3) there is doubt as to the best therapeutic measures to be utilized, and (4) there is a question of criminal action.

- A satisfactory consultation includes examination of the patient and the record. A written opinion signed by the consultant is included in the medical record. When operative procedures are involved, the consultation note, except in an emergency, is recorded prior to operation.
- The patient's physician is responsible for requesting consultations when indicated. It is the duty of the medical staff, through its chiefs of service and executive committee, to make certain that members of the staff do not fail in the matter of calling consultants as needed.

Factor 1. Routine procedures such as an X-ray examination, electrocardiogram determination, tissue examination, and proctoscopic and cystoscopic procedures are not normally considered to be consultations.

MEMBERSHIP

Standard D

Staff appointments are made by the governing body, taking into account recommendations made by the active staff.

Factor 1. The governing body has the legal right to appoint the medical staff and the moral obligation to appoint only those physicians who are judged by their fellows to be of good character and qualified and competent in their respective fields.

Factor 2. Reappointments are made periodically, and recorded in the minutes of the governing body. Reappointment policies provide for a periodic appraisal of each member of the staff, including consideration of his physical and mental capabilities. Recommenda-

tions for such reappointments are noted either in the credential committee or medical staff meetings' minutes.

Factor 3. Temporary staff privileges (for example, locum tenens) are granted for a limited period if the physician is otherwise properly qualified for such.

Standard E

Members of the staff are qualified legally, professionally, and ethically for the positions to which they are appointed.

Factor 1. To select its members and delineate privileges, the hospital medical staff has a system, based on definite workable standards, to evaluate each applicant by its credentials committee (or in small hospitals, committee-of-the-whole) which makes recommendations to the medical staff and to the governing body.

Factor 2. Privileges are extended to duly licensed qualified physicians to practice in the appropriate fields of general practice, internal medicine, surgery, pediatrics, obstetrics, gynecology, and other recognized and accepted fields according to individual qualifications.

Factor 3. Criteria for selection are individual character, competence, training, experience, and judgment.

Factor 4. Under no circumstances is the accordance of staff membership or professional privileges in the hospital dependent solely upon certification, fellowship, or membership in a specialty body or society. All qualified candidates are considered by the credentials committee.

Factor 5. The scope of privileges to be accorded the physician is indicated. The privileges of each staff member are specifically stated or the medical staff defines a classification system. If a system involving classification is used, the scope of the divisions is well defined, and the standards which must be met by the applicant are clearly stated for each category.

Standard F

Regardless of any other categories having privileges in the hospital, there is an active staff, properly organized, which performs all the organizational duties pertaining to the medical staff. These include:

- Maintenance of the proper quality of all medical care and treatment in the hospital;
- Organization of the medical staff, including adoption of rules and regulations for its government (which require the approval of the governing body), election of its officers or recommendations to the governing body for appointment of the officers, and recommendations to the governing body upon all appointments to the staff and grants of hospital privileges; and

- Other recommendations to the governing body upon matters within the purview of the medical staff.

Standard G

In larger hospitals, and in some smaller hospitals, the medical staff may include one or more of the following categories in addition to the active staff, but this in no way modifies the duties and responsibilities of the active staff.

- **Honorary Staff.** The honorary staff is composed of former active staff, retired or emeritus, and other physicians of reputation whom it is desired to honor.
- **Consulting Staff.** The consulting staff is composed of recognized specialists willing to serve in such capacity. A member of the consulting staff may also be a member of the active staff, but only if the two appointments are made.
- **Associate Staff.** The associate staff is composed of those members who use the hospital infrequently or those less experienced members undergoing a period of probation before being considered for appointment to the active staff.
- **Courtesy Staff.** The courtesy staff is composed of those who desire to attend patients in the hospital but who, for some reason not disqualifying, are ineligible for appointment in another category of the staff.

ORGANIZATION

Standard H

There are such officers as may be necessary for the government of the staff. These officers are members of the active staff and are elected by the active staff, unless this is precluded by hospital policy.

Factor 1. The officers are elected from and by the active staff or appointed in accordance with hospital policy on the basis of ability and willingness to assume responsibility and devote time to the office.

Factor 2. Where officers are elected, all election rules are carefully spelled out in the bylaws. The election is an open one and most preferably by secret ballot.

Factor 3. The chief of staff:

- (i) Has direct responsibility for the organization and administration of the medical staff, in accordance with the terms of the medical staff constitution, bylaws, rules, and regulations; (ii) In all medico-administrative matters, acts in coordination and cooperation with

the hospital administrator in giving effect to the policies adopted by the governing body; and (iii) Is responsible for the functioning of the clinical organization of the hospital and keeps or causes to be kept careful supervision over the clinical work in all departments.

Standard I

Bylaws are adopted to govern and enable the medical staff to carry out its responsibilities.

Factor 1. The bylaws of the medical staff are a precise and clear statement of the policies under which the medical staff regulates itself.

Factor 2. Medical staff bylaws, rules and regulations include the following:

(i) A descriptive outline of medical staff organization; (ii) A statement of the necessary qualifications which physicians must possess to be privileged to work in the hospital, and of the duties and privileges of each category of medical staff; (iii) A procedure for granting and withdrawing privileges to physicians; (iv) A mechanism for appeal of decisions regarding medical staff membership and privileges; (v) A definite and specific statement forbidding the practice of the division of fees under any guise whatsoever; (vi) Provision for regular meetings of the medical staff; (vii) Provision for keeping accurate and complete clinical records; (viii) A statement to the effect that the physician in charge of the patient is responsible for seeing that all tissue removed at operation is delivered to the hospital pathologist, and that a routine examination and report is made of such tissue; (ix) Provision for routine examination of all patients upon admission and recording of preoperative diagnosis prior to surgery; (x) A ruling permitting a surgical operation only on consent of the patient or his legal representative, except in emergencies; (xi) A statement providing that, except in emergency, consultation is required as outlined above; (xii) A regulation requiring that physicians' orders be recorded and signed; and (xiii) If dentists and oral surgeons are to be admitted to staff membership, the necessary qualifications, status, privileges and rights of this group are stated in the bylaws.

COMMITTEES

The structure of committee organization is a decision to be made by the medical staff as long as the required committee functions are carried out. A small staff may wish to function as a committee of the whole. Others may wish to combine committee functions in two or three committees.

Standard J

The executive committee (or its equivalent) coordinates the activities and general policies

of the various departments, acts for the staff as a whole under such limitations as may be imposed by the staff, and receives and acts upon the reports of the medical records, tissue, and such other committees as the medical staff may designate.

Factor 1. The committee meets at least once a month, exclusive of the summer months, and maintains a permanent record of its proceedings and actions.

Factor 2. Committee membership is made up of the officers of the medical staff, chiefs of major departments or services, and one or more members elected at large from the active medical staff.

Factor 3. Its functions and responsibilities include:

(i) Considering and recommending action to the administrator on all matters which are of a medical-administrative nature; (ii) Investigating any reports of breach of ethics by members of the medical staff, as referred to this committee by the credentials committee; and (iii) Acting as the program committee for staff meetings, unless this responsibility is delegated to a specific committee.

Standard K

The credentials committee (or its equivalent) reviews applications for appointment and re-appointment to all categories of the staff.

They delineate the privileges to be extended to the applicant and make appropriate recommendations to the governing body according to the procedure outlined in the hospital's medical staff bylaws.

Factor 1. The committee makes recommendations for initial appointment, hospital privileges, promotions, and demotions.

Factor 2. The committee is advisory and investigative and makes recommendations only. It is not given disciplinary or punitive powers.

Standard L

The joint conference committee (or its equivalent) is a medico-administrative advisory committee and the official means of liaison among the medical staff, the governing body, and the administrator. In the absence of a joint conference committee, a formal means of liaison between the governing body and medical staff is established.

Factor 1. A formal means of liaison exists even where there is medical staff representation on the governing body.

Factor 2. The committee meets at least four times per year and maintains a permanent record of its minutes.

Factor 3. Purposes of the committee include:

(i) Communications to keep the governing body, medical staff, and administration cognizant of pertinent actions taken or contemplated by one or the other; (ii) Consideration of plans for growth; and (iii) Consideration of issues affecting medical care which arise in the operation and affairs of the hospital.

Standard M

The medical records committee (or its equivalent) supervises the maintenance of medical records at the required standard of completeness. On the basis of documented evidence, the committee also reviews and evaluates the quality of medical care given the patient.

Factor 1. The committee meets at least once a month exclusive of the summer months, and submits a written report to the executive committee.

Factor 2. The committee's members represent a cross section of the clinical services. In large hospitals, each major clinical department may have its own committee.

Factor 3. Membership is staggered so that experienced committee physicians are always included. Senior residents may serve on this committee.

Factor 4. Review of the record for completeness can be performed for the most part by the medical record librarian. In addition, on-the-spot scanning of current inpatient records for completeness is done on the floors.

Factor 5. The quality of patient care is evaluated from the documentation on the chart. In some hospitals, this function may be given to an "audit" or "evaluation" committee.

Factor 6. The committee:

(i) Makes recommendations to the medical staff for the approval of, use of, and any changes in form or format of the medical record; (ii) Advises and recommends policies for medical record maintenance and supervises the medical records to insure that details are recorded in the proper manner and that sufficient data are present to evaluate the care of the patient; (iii) Ensures that there is proper filing, indexing, storage, and availability of all patient records; and (iv) With the aid of legal counsel, advises and develops policies to guide the medical record librarian, medical staff, and administration so far as matters of privileged communication and legal release of information are concerned.

Standard N

The tissue committee (or its equivalent) reviews and evaluates all surgery performed in the

hospital on the basis of agreement or disagreement among the preoperative, postoperative, and pathological diagnoses, and on the acceptability of the procedure undertaken.

Factor 1. The committee meets at least once a month, exclusive of the summer months, and submits a written report to the executive committee.

Factor 2. This committee's work includes continuing education through such mechanisms as utilization of its findings in the form of hypothetical cases or review of cases by category at staff meetings or publishing in coded form physicians' standings in the hospital regarding percentage of cases in which normal tissue is removed.

Standard O

Meetings of the medical staff are held to review, analyze, and evaluate the clinical work of its members.

- The number and frequency of medical staff meetings are determined by the active staff and clearly stated in the bylaws of the staff.
- Attendance requirements for each individual member of the staff and for the total attendance at each meeting are clearly stated in the bylaws of the staff. Attendance records are kept.
- Adequate minutes of all meetings are kept.
- The method adopted to insure adequate evaluation of clinical practice in the hospital is determined by the medical staff and clearly stated in the bylaws. Any one of the following three methods will fulfill this requirement:
 - (1) Monthly meetings of the active staff;
 - (2) Monthly departmental conferences in those hospitals where the clinical services are well organized and each department is large enough to meet as a unit; and
 - (3) Monthly meetings of the medical records and tissue committees at which the quality of medical work is adequately appraised, action is taken by the executive committee, and reports are made to the active staff.

Factor 1. Absence of a staff member from more than the specified percentage of regular meetings for the year, unless excused by the executive committee for just cause such as absence from the community or sickness, is considered as resignation from the active medical staff.

Factor 2. Staff and departmental meetings are held for the purpose of reviewing the medical care of patients within the hospital and those recently discharged.

Factor 3. Minutes of such meetings give evidence of the following:

(i) A review of the clinical work done by the staff on at least a monthly basis; this includes consideration of selected deaths, unimproved cases, infections, complications, errors in diagnosis, results of treatment, and review of transfusions; (ii) Consideration of the hospital statistical report on admissions, discharge, clinical classifications of patients, autopsy rates, hospital infections, and other pertinent hospital statistics; (iii) Short synopsis of each case discussed; (iv) Names of discussants; and (v) Duration of meeting.

DEPARTMENTALIZATION

Standard P

Division of the staff into services or departments to fulfill medical staff responsibilities promotes efficiency and is recommended in general hospitals with 75 or more beds. Each autonomous service or department is organized and functions as a unit.

- Medical staff members of each service or department are qualified by training and demonstrated competence and are granted privileges commensurate with their individual abilities.
- The chief of service or department is a member of the service or department qualified by training, experience, and administrative ability for the position. He is responsible for the administration of the department, for the general character of the professional care of patients, and for making recommendations as to the qualifications of its members. He also makes

recommendations to the administration as to the planning of hospital facilities, equipment, routine procedures, and any other matters concerning patient care.

- In those hospitals where the review and evaluation of clinical practice are done by committees of the medical staff or by monthly meetings of the entire staff, departmental meetings are optional. In those hospitals where the clinical review is done by the departments, each service or department meets at least once a month.

Records of these meetings are kept and become part of the records of the medical staff.

Factor 1. Selection of each chief of service by the governing body is never made without first obtaining reliable medical advice.

Factor 2. Duties and responsibilities of the chief include, in addition to those cited above:

- (i) Responsibility for arranging and expediting inpatient and outpatient departmental programs embracing organization, educational activities, supervision, and evaluation of the clinical work; (ii) Responsibility for enforcement of the hospital medical staff bylaws, rules, and regulations, with special attention to those pertaining to his department; (iii) Cooperation with the hospital administration with respect to the purchase of supplies and equipment and in formulating special regulations and policies applicable to his department, such as standing orders and techniques; (iv) Maintaining the quality of the medical records in his department; and (v) Representing his department, in a medical advisory capacity, to the administration and governing body.



Condition of Participation
V. NURSING DEPARTMENT

THE HOSPITAL HAS AN ORGANIZED NURSING DEPARTMENT. A LICENSED REGISTERED PROFESSIONAL NURSE IS ON DUTY AT ALL TIMES AND PROFESSIONAL NURSING SERVICE IS AVAILABLE FOR ALL PATIENTS AT ALL TIMES.

Standard A

There is a well organized departmental plan of administrative authority with delineation of responsibilities and duties of each category of nursing personnel.

Factor 1. The delineation of responsibilities and duties for each category of the nursing staff may be in the form of a written job description for each category.

Standard B

There is an adequate number of licensed registered professional nurses to meet the following minimum staff requirements:

- Director of the department;
- Assistants to the director for evening and night services;
- Supervisory and staff personnel for each department or nursing unit to insure the immediate availability of a registered professional nurse for bedside care of any patient when needed; and
- Registered professional nurse on duty at all times and available for all patients on a 24-hour basis.

Factor 1. The staffing pattern insures the availability of registered professional nursing care for all patients on a 24-hour basis every day.

Factor 2. If a licensed practical nurse or nursing aide is on duty during the evening and night hours in a ward with patients who do not generally need skilled nursing care, there is a registered professional nurse supervisor who makes frequent rounds and is immediately available to give skilled nursing care when needed. She is free to render bedside care and is not occupied in the operating room, delivery room, or emergency room for long periods of time.

Factor 3. The ratio of registered professional nurses to patients together with the ratio of registered professional nurses to other nursing personnel is adequate

to provide proper supervision of patient care and staff performance, taking into consideration the characteristics of the patient load.

Factor 4. A registered professional nurse assigns the nursing care of each patient to other nursing personnel in accordance with the patient's needs and the preparation and competence of the nursing staff available.

Standard C

There are other nursing personnel in sufficient numbers to provide nursing care not requiring the service of a registered professional nurse.

Factor 1. The training and supervision of these personnel are continually planned and carried out to enable them to perform effectively the duties which are assigned to them.

Standard D

There are adequate nursing personnel for the surgical suite, clinics, and other services of the hospital in keeping with their size and degree of activity.

Factor 1. A registered professional nurse is in charge of the operating rooms.

Factor 2. Surgical technicians and licensed practical nurses may be permitted to serve as "scrub nurses" under the direct supervision of a registered professional nurse; they are not permitted to function as circulating nurses in the operating rooms.

Standard E

Individuals selected for the nursing staff are qualified by education, experience, and demonstrated ability for the positions to which they are appointed.

Factor 1. The director of nursing makes decisions relative to the selection and promotion of nursing personnel based on their qualifications and capabilities and recommends the termination of employment when this is necessary.

Factor 2. The educational and experiential qualifications of the director of nursing, her assistants, and supervisors are commensurate with the size and complexity of the hospital.

Factor 3. The functions and qualifications of nursing personnel are clearly defined in relation to the duties and responsibilities delegated to them.

Factor 4. There is a procedure to insure that hospital nursing personnel for whom licensure is required do have valid and current licensure.

Factor 5. Personnel records including application forms and verification of credentials are on file.

Factor 6. New employees are oriented to the hospital, nursing service, and their jobs.

Standard F

There are well established working relationships with other services of the hospital, both administrative and professional.

Factor 1. Registered professional nurses confer with the physicians relative to patient care.

Factor 2. Interdepartmental policies affecting nursing service and nursing care to patients are made jointly with the director of nursing.

Factor 3. There are established procedures for scheduling laboratory and X-ray examinations, for ordering, securing and maintaining supplies and equipment needed for patient care, for ordering diets, etc.

Standard G

There is constant review and evaluation of the nursing care provided for patients. There are written nursing care procedures and written nursing care plans for patients.

Factor 1. Nursing care policies and procedures are written and consistent with generally accepted practice and are reviewed and revised as necessary to keep pace with best practice and new knowledge.

Factor 2. A registered professional nurse plans, supervises, and evaluates the nursing care for each patient.

Factor 3. Nursing care plans are kept current daily. Plans indicate nursing care needed, how it is to be accomplished, and methods, approaches and modifications

necessary to insure best results for the patient.

Factor 4. Nursing notes are informative and descriptive of the nursing care given and include information and observations of significance so that they contribute to the continuity of patient care.

Factor 5. Only (a) a licensed physician or a registered professional nurse or (b) under the direct supervision of a registered professional nurse, a licensed practical nurse, a student nurse in an approved school of nursing, or a psychiatric technician are permitted to administer medications, and in all instances, in accordance with the Nurse Practice Act of each State.

Factor 6. All medical orders are in writing and signed by the physician. Telephone orders are used sparingly, are given only to the registered professional nurse, and are signed or initialed by the physician as soon as possible.

Factor 7. Blood transfusions and intravenous medications are administered in accordance with State law. If administered by registered professional nurses, they are administered only by those who have been specially trained for this duty.

Factor 8. There is an effective hospital procedure for reporting transfusion reactions and adverse drug reactions.

Standard H

Meetings of the registered professional nursing staff are held at least monthly to discuss patient care, nursing service problems, and administrative policies. The pattern for meetings may be by clinical departments, by categories of the staff, or by the staff as a whole. Minutes of all meetings are kept.

Factor 1. Minutes reflect the purpose of the staff meetings; e.g., review and evaluation of nursing care, ways of improving nursing service, discussion of nursing care plans for individual patients, consideration of specific nursing techniques and procedures, establishment and/or interpretation of nursing department policies, interpretation of administrative and medical staff policies, reports of meetings, etc.

Factor 2. Minutes are available to staff members either individually or are maintained in a central place.

Condition of Participation
VI. DIETARY DEPARTMENT

THE HOSPITAL HAS AN ORGANIZED DIETARY DEPARTMENT* DIRECTED BY QUALIFIED PERSONNEL.

Standard A

There is an organized department directed by qualified personnel and integrated with other departments of the hospital. There is a qualified dietician, full-time or on a consultation basis, and, in addition, administrative and technical personnel competent in their respective duties.

Factor 1. There are written policies and procedures for food storage, preparation, and service developed by a qualified dietician (preferably meeting the American Dietetic Association's standards for qualification).

Factor 2. The department is under the supervision of a qualified dietician who is responsible for quality food production, service, and staff education. The dietician serves on a full-time basis if possible or, in smaller hospitals, on a regular part-time supervising or consulting basis.

Factor 3. In the absence of a full-time dietician, there is a qualified person serving as full-time director of the department who is responsible for the daily management aspects of the department and the dietician visits the hospital at intervals to supervise and instruct personnel.

Factor 4. The number of professional dietitians is adequate considering the size of the facility and the scope and complexity of dietary functions.

Factor 5. Supervisors, other than dietitians, are assigned in numbers and with ability to provide a satisfactory span of control to meet the needs of the physical facilities and the organization as well as coverage for all hours of departmental operation.

Factor 6. The number of personnel, such as cooks, bakers, dishwashers, and clerks, is adequate to perform effectively all defined functions.

*A hospital which has a contract with an outside food management company may be found to meet the conditions of participation if the company has a therapeutic dietician who serves, as required by scope and complexity of the service, on a full-time, part-time, or consultant basis to the hospital and provided the company maintains the minimum standards as listed herein and provides for constant liaison with the hospital medical staff for recommendations on dietetic policies affecting patient treatment.

Factor 7. Written job descriptions of all dietary employees are available.

Factor 8. There is an inservice training program for dietary employees which includes the proper handling of food and personal grooming.

Standard B

Facilities are provided for the general dietary needs of the hospital. These include facilities for the preparation of special diets. Sanitary conditions are maintained in the storage, preparation, and distribution of food.

Factor 1. All dietary areas are appropriately located, adequate in size, well lighted, ventilated and maintained.

Factor 2. The type, size, and layout of equipment provides for ease of cleaning, optimal work-flow and adequate food production to meet the scope and complexity of the regular and therapeutic diet requirements of the patients.

Factor 3. Equipment and work areas are clean and orderly. Effective procedures for cleaning all equipment and work areas are followed consistently to safeguard the health of the patient.

Factor 4. Lavatories specifically for handwashing, including hot and cold running water, soap and approved disposable towels, are conveniently located throughout the department for use by food handlers.

Factor 5. There are procedures to control dietary employees with infections and open lesions. Routine health examinations at least meet local, State, or Federal codes for food service personnel.

Factor 6. The dietary department is routinely inspected and approved by State or local health agencies as a food handling establishment. Written reports of the inspection are on file at the hospital with notation made by the hospital of action taken to comply with recommendations.

Factor 7. Dry or staple food items are stored at least 12 inches off the floor in a ventilated room which is not subject to sewage or waste water back-flow, or

contamination by condensation, leakage, rodents or vermin.

Factor 8. All perishable foods are refrigerated at the appropriate temperature and in an orderly and sanitary manner.

Factor 9. Foods being displayed or transported are protected from contamination and held at proper temperatures in clean containers, cabinets or serving carts.

Factor 10. Dishwashing procedures and techniques are well developed, understood, and carried out in compliance with the State and local health codes and with periodic check on:

(i) Detergent dispenser operation; (ii) Washing, rinsing, and sanitizing temperatures and cleanliness of machine and jets; (iii) Routine bacterial counts on dishes, flatware, glasses, utensils and equipment; and (iv) Thermostatic controls.

Factor 11. All garbage and kitchen refuse which is not disposed of through a disposal is kept in leakproof nonabsorbent containers with close fitting covers and is disposed of daily in a manner that will not permit transmission of disease, a nuisance, or a breeding place for flies. All garbage containers are thoroughly cleaned inside and out each time emptied.

Standard C

There is a systematic record of diets, correlated, when appropriate, with the medical records.

Factor 1. Therapeutic diets are prescribed in written orders on the chart by the physician and are as instructive, accurate, and complete as possible; for example, bland low residue diet or, if a diabetic diet is ordered,

the exact amounts of carbohydrate, protein, and fat allowed are noted.

Factor 2. Nutrition needs are met in accordance with the current Recommended Dietary Allowances of the Food and Nutrition Board, National Research Council, and in accordance with physician's orders.

Factor 3. The dietician has available an up-to-date manual of regimens for all therapeutic diets, approved jointly by the dietician and medical staff, which is available to dietary supervisory personnel. Diets served to patients are in compliance with these established diet principles.

Factor 4. The dietician correlates and integrates the dietary aspects of patient care with the patient and patient's chart through such methods as patient instruction and recording diet histories and participates appropriately in ward rounds and conferences, sharing specialized knowledge with others of the medical team.

Standard D

Departmental and interdepartmental conferences are held periodically.

Factor 1. The director of dietetics attends and participates in meetings of heads of departments and functions as a key member of the hospital staff.

Factor 2. The director of dietetics has regularly scheduled conferences with the administrator or his designee to keep him informed, seek his counsel, and present program plans for mutual consideration and solution.

Factor 3. Conferences are held regularly within the department at all levels of responsibility to disseminate information, interpret policy, solve problems, and develop procedures and program plans.

Condition of Participation
VII. MEDICAL RECORD DEPARTMENT

THE HOSPITAL HAS A MEDICAL RECORD DEPARTMENT WITH ADMINISTRATIVE RESPONSIBILITY FOR MEDICAL RECORDS. A MEDICAL RECORD IS MAINTAINED, IN ACCORDANCE WITH ACCEPTED PROFESSIONAL PRINCIPLES, FOR EVERY PATIENT ADMITTED FOR CARE IN THE HOSPITAL.

ADMINISTRATIVE RESPONSIBILITIES

Standard A

A medical record is maintained for every patient admitted for care in the hospital. Such records are kept confidential.

Factor 1. Only authorized personnel have access to the record.

Factor 2. Written consent of the patient is presented as authority for release of medical information.

Factor 3. Medical records generally are not removed from the hospital environment except upon subpoena.

Standard B

Records are preserved, either in the original or by microfilm, for a period of time not less than that determined by the statute of limitations in the respective State.

Standard C

Qualified personnel adequate to supervise and conduct the department are provided.

Factor 1. Preferably a registered medical record librarian heads the department. If such a professionally qualified person is not in charge of medical records, a qualified consultant or trained part-time medical record librarian organizes the department, trains the regular personnel, and makes periodic visits to the hospital to evaluate the records and the operation of the department.

Factor 2. A sufficient number of regular full-time and part-time employees are available so that medical record services may be provided as needed. In some hospitals this can mean around-the-clock coverage.

Standard D

A system of identification and filing to insure the prompt location of a patient's medical record is maintained.

Factor 1. Index cards bear at least the full name of the patient, the address, the birthdate, and the medical record number.

Factor 2. Filing equipment and space are adequate to house the records and facilitate retrieval.

Factor 3. A unit record is maintained so that both in- and out-patient treatment are in one folder.

Standard E

All clinical information pertaining to a patient's stay is centralized in the patient's record.

Factor 1. The original of all reports is filed in the medical record.

Factor 2. All reports or records are completed and filed within a period consistent with good medical practice and not longer than 15 days following discharge.

Standard F

Records are indexed according to disease, operation, and physician and are kept up-to-date. For indexing, any recognized system may be used.

Factor 1. As additional indices become appropriate due to advances in medicine, their use is adopted.

Factor 2. The index lists on a card (or other systematic record) for a specific disease or operation, according to a recognized nomenclature, all essential data on each patient having that particular condition. "Essential data" includes at least the medical record number of the patient so that the record may be located. All conditions for which the patient is treated during the hospitalization are so indexed.

Factor 3. In hospitals using automatic data processing, indexes may be kept on punch cards or reproduced on sheets kept in books.

Factor 4. Diagnoses and operations are expressed in terminology which describes the morbid condition both

as to site and etiological factors or the method of procedure.

Factor 5. Indexing is current within 6 months following discharge of the patient.

MEDICAL STAFF RESPONSIBILITIES

Standard G

The medical records contain sufficient information to justify the diagnosis and warrant the treatment and end results. The medical records contain the following information:

- Identification data.
- Chief complaint.
- Present illness.
- Past history.
- Family history.
- Physical examination.
- Provisional diagnosis.
- Clinical laboratory reports.
- X-ray reports.
- Consultations.
- Treatment: medical and surgical.
- Tissue report.
- Progress notes.
- Final diagnosis.
- Discharge summary.
- Autopsy findings.

Factor 1. The chief complaint includes a concise statement of complaints which led the patient to consult his physician and the date of onset and duration of each.

Factor 2. The physical examination statement includes all positive and negative findings resulting from an inventory of systems.

Factor 3. The provisional diagnosis is an impression (diagnosis) reflecting the examining physician's evaluation of the patient's condition based mainly on physical findings and history.

Factor 4. A consultation report is a written opinion signed by the consultant, including his findings on physical examination of the patient.

Factor 5. All diagnostic treatment procedures are recorded in the medical record.

Factor 6. Tissue reports include a report of microscopic findings if hospital regulations require that

microscopic examination be done. If only gross examination is warranted a statement that the tissue has been received and a gross description are made by the laboratory and filed in the medical record.

Factor 7. Progress notes give a chronological picture of the patient's progress and are sufficient to delineate the course and results of treatment. The condition of the patient determines the frequency with which they are made.

Factor 8. A definitive final diagnosis is expressed in terminology of a recognized system of disease nomenclature.

Factor 9. The discharge summary is a recapitulation of the significant findings and events of the patient's hospitalization and his condition on discharge.

Factor 10. Autopsy findings in a complete protocol are filed in the record when an autopsy is performed.

Factor 11. A chronological summary of the patient's record is maintained in the front of the chart.

Standard H

Only members of the medical staff and the house staff are competent to write or dictate medical histories and physical examinations.

Standard I

Records are authenticated and signed by a licensed physician.

Factor 1. Every physician signs the entries which he himself makes.

Factor 2. A single signature on the fact sheet of the record does not suffice to authenticate the entire record.

Factor 3. In hospitals with house staff, the attending physician countersigns at least the history and physical examination and summary written by the house staff.

Standard J

Current records and those on discharged patients are completed promptly.

Factor 1. Current records are completed within 24-48 hours following admission.

Factor 2. Records of patients discharged are complete within 15 days following discharge.

Factor 3. If a patient is readmitted within a month's time for the same condition, reference to the previous history with an interval note and physical examination suffices.

Condition of Participation

VIII. PHARMACY OR DRUG ROOM

THE HOSPITAL HAS A PHARMACY DIRECTED BY A REGISTERED PHARMACIST OR A DRUG ROOM UNDER COMPETENT SUPERVISION. THE PHARMACY OR DRUG ROOM IS ADMINISTERED IN ACCORDANCE WITH ACCEPTED PROFESSIONAL PRINCIPLES.

Standard A

There is a pharmacy directed by a registered pharmacist or a drug room under competent supervision.

Factor 1. The pharmacist is trained in the specialized functions of hospital pharmacy.

Factor 2. The pharmacist is responsible to the administration of the hospital for developing, supervising, and coordinating all the activities of the pharmacy department.

Factor 3. If there is a drug room with no pharmacist, prescriptions are compounded by a qualified pharmacist elsewhere, and only storing and distributing are done in the drug room. A consulting pharmacist assists in drawing up the correct procedures, rules, and regulations for the drug room.

Standard B

Facilities are provided for the storage, safeguarding, preparation, and dispensing of drugs.

Factor 1. Drugs are issued to floor units in accordance with approved policies and procedures.

Factor 2. Drug cabinets on the nursing units are routinely checked by the pharmacist. All floor stocks are properly controlled.

Factor 3. There is adequate space for all pharmacy operations and the storage of drugs at a satisfactory location provided with proper lighting, ventilation, and temperature controls.

Factor 4. If there is a pharmacy, equipment is provided for the compounding and dispensing of drugs.

Factor 5. Special locked storage space is provided to meet the legal requirements for storage of narcotics, alcohol, and other prescribed drugs.

Standard C

Personnel competent in their respective duties are provided in keeping with the size and activity of the department.

Factor 1. The pharmacist is assisted by an adequate number of additional registered pharmacists and such

other personnel as the activities of the pharmacy may require to insure quality pharmaceutical services.

Factor 2. The pharmacy, depending upon the size and scope of its operations, is staffed by the following categories of personnel:

(i) Chief pharmacist; (ii) One or more assistant chief pharmacists; (iii) Staff pharmacists; (iv) Pharmacy trainees (where a program has been activated); (v) Nonprofessionally trained pharmacy helpers; (vi) Clerical help.

Factor 3. Provision is made for emergency pharmaceutical services.

Factor 4. If the hospital has only a drug room, a designated individual(s) has responsibility for its operation.

Standard D

Records are kept of the transactions of the pharmacy (or drug room) and correlated with other hospital records where indicated. Such special records are kept as are required by law.

Factor 1. The pharmacy establishes and maintains, in cooperation with the accounting department, a satisfactory system of records and bookkeeping in accordance with the policies of the hospital for:

(i) Maintaining adequate control over the requisitioning and dispensing of all drugs and pharmaceutical supplies; (ii) Charging patients for drugs and pharmaceutical supplies.

Factor 2. A record of the stock on hand and of the dispensing of all narcotic drugs is maintained in such a manner that the disposition of any particular item may be readily traced.

Standard E

Policies are established to control the administration of toxic or dangerous drugs with specific reference to the duration of the order and the dosage.

Factor 1. The medical staff has established a written policy that all toxic or dangerous medications, not spe-

cifically prescribed as to time or number of doses, will be automatically stopped after a reasonable time limit set by the staff. The classifications ordinarily thought of as toxic or dangerous drugs are narcotics, sedatives, anticoagulants, and antibiotics.

Standard F

There is a committee of the medical staff to confer with the pharmacist in the formulation of policies.

Factor 1. A pharmacy and therapeutics committee (or equivalent committee), composed of physicians and pharmacists, is established in the hospital and serves as the liaison between the medical staff and the pharmacist.

Factor 2. The committee assists in the formulation of broad professional policies regarding the procurement, distribution, use, safety procedures, and other matters relating to drugs in hospitals.

Factor 3. The committee performs the following specific functions:

(i) Serves as an advisory group to the hospital medical staff and the pharmacist on matters pertaining to the choice of drugs; (ii) Develops and reviews periodically a formulary or drug list accepted for use in the hospital; (iii) Establishes standards concerning the use and control of experimental drugs and research in the use of recognized drugs; (iv) Evaluates clinical data concerning new drugs or preparations requested for use in the hospital; (v) Makes recommendations

concerning drugs to be stocked on the nursing unit floors and by other services; and (vi) Prevents unnecessary duplication in stocking the same basic drug and its preparation.

Factor 4. The committee meets at least quarterly and reports to the executive committee and the medical staff.

Standard G

Drugs dispensed are included (or approved for inclusion) in the United States Pharmacopoeia, National Formulary, United States Homeopathic Pharmacopoeia, New Drugs, or Accepted Dental Remedies (except for any drugs unfavorably evaluated therein), or are approved for use by the pharmacy and drug therapeutics committee (or equivalent committee) of the hospital staff.

Factor 1. The pharmacist, with the advice and guidance of the pharmacy and therapeutics committee, is responsible for specifications as to quality, quantity, and source of supply of all drugs.

Factor 2. There is available a formulary or list of drugs accepted for use in the hospital which is developed and amended at regular intervals by the pharmacy and therapeutics committee (or equivalent committee) with the cooperation of the pharmacist (consulting or otherwise) and the administration.

Factor 3. The pharmacy or drug room is adequately supplied with preparations so approved.

Condition of Participation

IX. LABORATORIES

THE HOSPITAL HAS A WELL ORGANIZED, ADEQUATELY SUPERVISED CLINICAL LABORATORY WITH THE NECESSARY SPACE, FACILITIES AND EQUIPMENT TO PERFORM THOSE SERVICES COMMENSURATE WITH THE HOSPITAL'S NEEDS FOR ITS PATIENTS. ANATOMICAL PATHOLOGY SERVICES AND BLOOD BANK SERVICES ARE AVAILABLE EITHER IN THE HOSPITAL OR BY ARRANGEMENT WITH OTHER FACILITIES.

CLINICAL LABORATORIES

Standard A

Clinical laboratory services adequate for the individual hospital are maintained in the hospital.

Factor 1. The extent and complexity of service are commensurate with the size, scope, and nature of the hospital, and the demands of the medical staff upon the laboratory.

Factor 2. Basic laboratory services necessary for routine examinations are available regardless of the size, scope, and nature of the hospital.

Factor 3. Necessary space, facilities and equipment to perform both the basic minimum and all other services are provided by the hospital.

Factor 4. All equipment is in good working order, routinely checked, and precise in terms of calibration.

Standard B

Provision is made to carry out adequate clinical laboratory examinations including chemistry, microbiology, hematology, serology, and clinical microscopy.

Factor 1. Some or all of these services may be provided under arrangements by the hospital with a laboratory which is certified to provide these services for the Health Insurance for the Aged Program.

Factor 2. In the case of work performed by an outside laboratory, the original report from this laboratory is contained in the medical record.

Standard C

Facilities and services are available at all times.

Factor 1. Adequate provision is made for assuring the availability of emergency laboratory services, either in

the hospital or under arrangements with a laboratory which is certified for participation in the Health Insurance for the Aged Program. Such services are available 24 hours a day, 7 days a week, including holidays.

Factor 2. Where services are provided by an outside laboratory, the conditions, procedures, and availability of work done are in writing and available in the hospital.

Standard D

Personnel adequate to supervise and conduct the services are provided.

Factor 1. Services are under the supervision of a physician with training and experience in clinical laboratory services or a laboratory specialist qualified by a doctoral degree.

Factor 2. The laboratory does not perform procedures and tests which are outside the scope of training of the laboratory personnel.

Factor 3. There is a sufficient number of clinical laboratory technologists, preferably registered by the American Society of Clinical Pathology, to promptly and proficiently perform the tests requested of the laboratory.

Standard E

Routine examinations required on all admissions are determined by the medical staff. These include at least a urinalysis and a hemoglobin or hematocrit.

Factor 1. Required tests upon admission, as approved by the medical staff, are consistent with the scope and nature of the hospital.

Factor 2. The required list of tests is in written form and available to all members of the medical staff.

Standard F

Signed reports are filed with the patient's medical record and duplicate copies kept in the department.

Factor 1. The laboratory director is responsible for the laboratory report.

Factor 2. A copy of the clinical laboratory report is signed by the technologist.

Factor 3. There is a procedure for assuring that all requests for tests are ordered and signed by a physician.

ANATOMICAL PATHOLOGY

Standard G

Services of a pathologist are provided as indicated by the needs of the hospital.

Factor 1. Services are under the direct supervision of a pathologist on a full-time, regular part-time or regular consultative basis. If the latter pertains, the hospital provides for, at a minimum, monthly consultative visits by a pathologist.

Factor 2. The pathologist participates in staff, departmental and clinicopathologic conferences.

Factor 3. The pathologist is responsible for the qualifications of his staff and their inservice training.

Standard H

All tissues removed at operation are sent for examination. The extent of examination is determined by the pathology department.

Factor 1. All tissues removed from patients at surgery are macroscopically, and if necessary, microscopically examined by the pathologist.

Factor 2. The pathologist or designated physician, in his absence, is responsible for verifying the receipt of tissues for examinations.

Factor 3. A list of tissues which routinely require microscopic examination is developed in writing by the pathologist or designated physician with the approval of the medical staff.

Factor 4. A tissue file is maintained in the hospital.

Factor 5. In the absence of a pathologist or suitable physician substitute, there should be an established plan for sending to a pathologist outside the hospital all tissues requiring examination.

Factor 6. Arrangements for tissue examinations done outside the hospital are made with a laboratory which is certified to provide this service for the Health Insurance for the Aged Program.

Standard I

Signed reports of tissue examinations are filed with the patient's medical record and duplicate copies kept in the department.

Factor 1. All reports of macro and microscopic examinations performed are signed by the pathologist or designated physician.

Factor 2. Provision is made for the prompt filing of examination results in the patient's medical record and notification of the physician requesting the examination.

Factor 3. Duplicate copies of the examination reports are filed in the laboratory in a manner which permits ready identification and accessibility.

BLOOD BANK SERVICES

Standard J

Facilities for procurement, safekeeping, and transfusion of blood and blood products are provided or readily available.

Factor 1. The hospital maintains, as a minimum, proper blood storage facilities under adequate control and supervision of the pathologist or other authorized physician.

Factor 2. For emergency situations the hospital maintains at least a minimum blood supply in the hospital at all times, can obtain blood quickly from community blood banks or institutions, or has an up-to-date list of donors and equipment necessary to bleed them.

Factor 3. Where the hospital depends on outside blood banks, there is an agreement governing the procurement, transfer and availability of blood which is reviewed and approved by the medical staff, administration and governing body.

Factor 4. There is provision for prompt blood typing and cross matching, either through the hospital or by arrangements with others on a continuous basis, under the supervision of a physician.

Factor 5. Blood storage facilities in the hospital have an adequate alarm system, which is regularly inspected and is otherwise safe and adequate.

Factor 6. Records are kept on file indicating the receipt and disposition of all blood provided to patients in the hospital.

Factor 7. Blood which has exceeded its expiration date is disposed of promptly.

Factor 8. A committee of the medical staff or its equivalent reviews all transfusions of blood or blood derivatives and makes recommendations concerning policies governing such practices.

Factor 9. The review committee investigates all transfusion reactions occurring in the hospital and makes recommendations to the medical staff regarding improvements in transfusion procedures.

Condition of Participation
X. RADIOLOGY DEPARTMENT

THE HOSPITAL HAS DIAGNOSTIC X-RAY FACILITIES AVAILABLE. IF THERAPEUTIC X-RAY SERVICES ARE ALSO PROVIDED, THEY, AS WELL AS THE DIAGNOSTIC SERVICES, MEET PROFESSIONALLY APPROVED STANDARDS FOR SAFETY AND PERSONNEL QUALIFICATIONS.

Standard A

The hospital maintains or has available radiological services according to needs of the hospital.

Factor 1. The hospital has diagnostic X-ray facilities available in the hospital building proper or in an adjacent clinic or medical facility that is readily accessible to the hospital patients, physicians, and personnel.

Standard B

The radiology department is free of hazards for patients and personnel.

Factor 1. Proper safety precautions are maintained against fire and explosion hazards, electrical hazards, and radiation hazards.

Factor 2. Periodic inspection is made by local or State health authorities or a radiation physicist, and hazards so identified are promptly corrected.

Factor 3. Radiation workers are checked periodically for amount of radiation exposure by the use of exposure meters or badge tests.

Factor 4. With fluoroscopes, attention is paid to modern safety design and good operating procedures; records are maintained of the output of all fluoroscopes.

Factor 5. Regulations based on medical staff recommendations are established as to the administration of the application and removal of radium element, its disintegration products, and other radioactive isotopes.

Standard C

Personnel adequate to supervise and conduct the services are provided, and the interpretation of radiological examinations is made by physicians competent in the field.

Factor 1. The hospital has a qualified radiologist, either full-time or part-time on a consulting basis, both

to supervise the department and to interpret films that require specialized knowledge for accurate reading. If the hospital is small, and a radiologist cannot come to the hospital regularly, selected X-ray films are sent to a radiologist for interpretation.

Factor 2. If the activities of the radiology department extend to radiotherapy, the physician in charge is appropriately qualified.

Factor 3. The amount of qualified radiologist and technologist time is sufficient to meet the hospital's requirements. A technologist is on duty or on call at all times.

Factor 4. The use of all X-ray apparatus is limited to personnel designated as qualified by the radiologist or by an appropriately constituted committee of the medical staff. The same limitation applies to personnel applying and removing radium element, its disintegration products, and radioactive isotopes. The use of fluoroscopes is limited to physicians.

Standard D

Signed reports are filed with the patient's record and duplicate copies kept in the department.

Factor 1. Requests by the attending physician for X-ray examination contain a concise statement of reason for the examination.

Factor 2. Reports of interpretations are written or dictated and signed by the radiologist.

Factor 3. X-ray reports and roentgenographs are preserved or microfilmed in accordance with the statute of limitations.



Condition of Participation

XI. MEDICAL LIBRARY

THE HOSPITAL HAS MODERN TEXTBOOKS AND CURRENT PERIODICALS RELATIVE TO THE CLINICAL SERVICES OFFERED.

Standard A

The hospital maintains a medical library according to the needs of the hospital.

Factor 1. The medical library is located in the hospital building and its contents are organized, easily accessible, and available at all times to the medical and nursing staffs.

Factor 2. The library contains modern textbooks in basic sciences and other current textbooks, journals, and magazines pertinent to the clinical services maintained in the hospital.



Condition of Participation

XII. COMPLEMENTARY DEPARTMENTS

PARTICIPATION IS NOT LIMITED TO HOSPITALS WHICH HAVE SURGERY, ANESTHESIOLOGY, DENTAL, OR REHABILITATION DEPARTMENTS OR SERVICES, BUT IF THESE DEPARTMENTS OR SERVICES ARE PRESENT, THERE ARE EFFECTIVE POLICIES AND PROCEDURES, IN ADDITION TO THOSE SET FORTH UNDER "MEDICAL STAFF DEPARTMENTALIZATION," RELATING TO THE STAFF AND THE FUNCTIONS OF THE SERVICE(S) IN ORDER TO ASSURE THE HEALTH AND SAFETY OF THE PATIENTS.

Standard A

The Department of Surgery has effective policies and procedures regarding surgical privileges, maintenance of the operating rooms, and evaluation of the surgical patient.

Factor 1. Surgical privileges are delineated for all physicians doing surgery in accordance with the competencies of each physician. A roster of physicians specifying the surgical privileges of each is kept in the confidential files of the operating room supervisor and in the files of the hospital administrator.

Factor 2. In any procedure with unusual hazard to life, there is present and scrubbed as first assistant a physician designated by the credentials committee as being qualified to assist in major surgery.

Factor 3. Second and third assistants at major operations, and first assistants at lesser operations may be nurses, aides, or technicians if designated by the hospital authorities as having sufficient training to properly and adequately assist at such procedures.

Factor 4. The operating room register is complete and up-to-date.

Factor 5. There is a complete history and physical work-up in the chart of every patient prior to surgery (whether the surgery is major or minor). If such has been transcribed, but not yet recorded in the patient's chart, there is a statement to that effect and an admission note by the physician in the chart.

Factor 6. A properly executed consent form for operation is in the patient's chart prior to surgery.

Factor 7. There are adequate provisions for immediate post-operative care.

Factor 8. An operative report describing techniques and findings is written or dictated immediately following surgery and signed by the surgeon.

Factor 9. All infections of clean surgical cases are recorded and reported to the administration. A procedure exists for the investigation of such cases.

Factor 10. The operating rooms are supervised by an experienced registered professional nurse.

Factor 11. The following equipment is available in the operating suites: call-in system, cardiac monitor, resuscitator, defibrillator, aspirator, thoracotomy set, and tracheotomy set.

Factor 12. The operating room suite and accessory services are so located that traffic in and out can be and is controlled and there is no through traffic.

Factor 13. Precautions are taken to eliminate hazards of explosions including use of shoes with conductive soles and prohibition of nylon garments.

Factor 14. Rules and regulations and/or policies related to the operating rooms are available and posted.

Standard B

The Department of Anesthesia has effective policies and procedures regarding staff privileges, the administration of anesthetics, and the maintenance of strict safety controls.

There is required for every patient:

- Preanesthetic physical examination by a physician with findings recorded within 48 hours of surgery;
- Anesthetic record on special form;
- Postanesthetic follow-up, with findings recorded, by an anesthesiologist or nurse anesthetist.

Factor 1. The Department of Anesthesia is responsible for all anesthetics administered in the hospital.

Factor 2. In hospitals where there is no Department of Anesthesia, the Department of Surgery assumes the

responsibility for establishing general policies and supervising the administration of anesthetics.

Factor 3. The director of the Department of Anesthesia preferably is also the director in charge of inhalation therapy. In any event, the inhalation therapy service is under the supervision of a qualified physician or physicians.

Factor 4. If anesthetics are not administered by a qualified anesthesiologist, they are administered by a physician anesthetist or a registered nurse anesthetist under the supervision of the operating physician. The hospital staff designates those persons qualified to administer anesthetics and delineates what the person is qualified to do.

Factor 5. The postanesthetic follow-up note is written three to 24 hours after the operation, notes any post-operative abnormalities or complications, and states the blood pressure, the pulse, the presence or absence of the swallowing reflex and cyanosis, and the general condition of the patient.

Factor 6. Safety precautions include:

- (i) Shockproof and sparkproof equipment;
- (ii) Humidity control;
- (iii) Proper grounding;
- (iv) Safety regulations posted;
- (v) Storage of flammable anesthetic and oxidizing gases meet the standards of the National Fire Protection Association Code.

Standard C

According to the procedure established for the appointment of the medical staff, one or more dentists may be appointed to the dental staff. If the dental service is organized, its organization is comparable to that of other services or departments. Whether or not the dental service is organized as a department, the following requirements are met:

- Members of the dental staff are qualified legally, professionally, and ethically for the positions to which they are appointed.
- Patients admitted for dental services are admitted by the dentist either to the Department of Dentistry or, if there is no department, to an organized clinical service.
- There is a physician in attendance who is responsible for the medical care of the patient throughout the hospital stay. A medical sur-

vey is done and recorded by a member of the medical staff before dental surgery is performed.

Factor 1. There are specific bylaws concerning the dental staff written as combined medical-dental staff bylaws or as separate or adjunct dental bylaws.

Factor 2. The staff bylaws, rules and regulations specifically delineate the rights and privileges of the dentists.

Factor 3. Complete records, both medical and dental, are required on each dental patient and shall be a part of the hospital records.

Standard D

The Rehabilitation, Physical Therapy, and Occupational Therapy Departments have effective policies and procedures relating to the organization and functions of the service(s) and are staffed by qualified therapists.

Factor 1. There may be a Rehabilitation Department including both physical and occupational therapy or there may be separate Physical Therapy and/or Occupational Therapy Departments.

Factor 2. The department head is a physiatrist or a physician with knowledge, experience, and capabilities to properly supervise and administer the department.

Factor 3. If physical therapy services are offered, there is at least one qualified physical therapist who is a graduate of a program in physical therapy approved by the American Medical Association or its equivalent. Other properly trained and supervised physical therapy technicians are sufficient to meet the needs of the department.

Factor 4. If occupational therapy services are offered, there is at least one registered occupational therapist (O.T.R.) and there are other properly trained and supervised occupational therapy personnel sufficient to meet the needs of the department.

Factor 5. Facilities and equipment for physical and occupational therapy are adequate to meet the needs of the services and are in good condition.

Factor 6. When physical therapy treatment is prescribed, there is an order written by the referring physician in the patient's chart stating the specific treatment desired.

Factor 7. After physical therapy treatment, definite note or documentation is made by the therapist as to the treatment rendered.

Condition of Participation
XIII. OUTPATIENT DEPARTMENT

PARTICIPATION IS NOT LIMITED TO HOSPITALS WHICH HAVE ORGANIZED OUTPATIENT DEPARTMENTS, BUT IF THEY ARE PRESENT, THERE ARE EFFECTIVE POLICIES AND PROCEDURES RELATING TO THE STAFF, FUNCTIONS OF THE SERVICE, AND OUTPATIENT MEDICAL RECORDS AND ADEQUATE FACILITIES IN ORDER TO ASSURE THE HEALTH AND SAFETY OF THE PATIENTS.

Standard A

The Outpatient Department is organized into sections (clinics) the number of which depends on the size and the degree of departmentalization of the medical staff, available facilities, and the needs of the patients for whom it accepts responsibility.

Factor 1. The outpatient department has appropriate cooperative arrangements and communications with community agencies such as other outpatient departments, public health nursing agencies, the department of health, and welfare agencies.

Factor 2. Clinics are integrated with corresponding inpatient services.

Factor 3. Clinics are maintained for the following purposes:

(i) Care of ambulatory patients unrelated to admission or discharge; (ii) Study of pre-admission patients; (iii) Follow-up of discharged hospital patients. *Factor 4.* Patients, on their initial visit to the department, receive a general medical evaluation and patients under continuous care receive an adequate periodic re-evaluation.

Factor 5. Established medical screening procedures are employed routinely.

Standard B

There are such professional and nonprofessional personnel as are required for efficient operation.

Factor 1. There is a physician responsible for the professional services of the department. Either this physician or a qualified administrator is responsible for administrative services.

Factor 2. A registered professional nurse is responsible for the nursing services of the department.

Factor 3. The number and type of other personnel employed reflect the volume and type of work carried out

and the type of patient served in the outpatient department.

Standard C

Facilities are provided to assure the efficient operation of the department.

Factor 1. The number of examination and treatment rooms is adequate in relation to the volume and nature of work performed.

Factor 2. Suitable facilities for necessary laboratory and other diagnostic tests are available either through the hospital or some other certified facility.

Standard D

Medical records are maintained, and correlated with other hospital medical records.

Factor 1. The outpatient medical record is filed in a location which insures ready accessibility to the physicians, nurses, and other personnel of the department.

Factor 2. The outpatient medical record is integrated with the patient's overall hospital record.

Factor 3. Information contained in the medical record is complete and sufficiently detailed relative to the patient's history, physical examination, laboratory and other diagnostic tests, diagnosis, and treatment to facilitate continuity of care.

Standard E

Conferences, both departmental and interdepartmental, are conducted to maintain close liaison between the various sections within the department and with other hospital services.

Factor 1. Minutes of staff and/or departmental meetings indicate that review of selected outpatient cases takes place and that there is integration of hospital inpatient and outpatient services.

Factor 2. The outpatient department has close working relationships with the medical and social service department.



Condition of Participation

XIV. EMERGENCY SERVICE OR DEPARTMENT

THE HOSPITAL HAS AT LEAST A PROCEDURE FOR TAKING CARE OF THE OCCASIONAL EMERGENCY CASE IT MIGHT BE CALLED UPON TO HANDLE. PARTICIPATION IS NOT LIMITED TO HOSPITALS WHICH HAVE ORGANIZED EMERGENCY SERVICES OR DEPARTMENTS, BUT IF THEY ARE PRESENT, THERE ARE EFFECTIVE POLICIES AND PROCEDURES RELATING TO THE STAFF, FUNCTIONS OF THE SERVICE, AND EMERGENCY ROOM MEDICAL RECORDS AND ADEQUATE FACILITIES IN ORDER TO ASSURE THE HEALTH AND SAFETY OF THE PATIENTS.

Standard A

The department or service is well organized, directed by qualified personnel, and integrated with other departments of the hospital.

Factor 1. There are written policies which are enforced to control emergency room procedures.

Factor 2. The policies and procedures governing medical care provided in the emergency service or department are established by and are a continuing responsibility of the medical staff.

Factor 3. The emergency service is supervised by a qualified member of the medical staff and nursing functions are the responsibility of a registered professional nurse.

Factor 4. The administrative functions are a responsibility of a member of the hospital administration.

Standard B

Facilities are provided to assure prompt diagnosis and emergency treatment.

Factor 1. Facilities are separate and independent of the operating rooms.

Factor 2. The location of the emergency service is in close proximity to an exterior entrance of the hospital.

Factor 3. Diagnostic and treatment equipment, drugs, supplies, and space, including a sufficient number of treatment rooms, are adequate in terms of the size and scope of services provided.

Standard C

There are adequate medical and nursing personnel available at all times.

Factor 1. The medical staff is responsible for insuring adequate medical coverage for emergency services.

Factor 2. Qualified physicians are regularly available at all times for the emergency service, either on duty or on call.

Factor 3. A physician sees all patients who arrive for treatment in the emergency service.

Factor 4. Qualified nurses are available on duty at all times and in sufficient number to deal with the number and extent of emergency services.

Standard D

Adequate medical records on every patient are kept.

Factor 1. The emergency room record contains:

(i) Patient identification; (ii) History of disease or injury; (iii) Physical findings; (iv) Laboratory and X-ray reports, if any; (v) Diagnosis; (vi) Record of treatment; (vii) Disposition of the case; (viii) Signature of a physician.

Factor 2. Medical records for patients treated in the emergency service are organized by a medical record librarian or her equivalent.

Factor 3. Where appropriate, medical records of emergency services are integrated with those of the inpatient and outpatient services.

Factor 4. A proper method of filing records is maintained.

Factor 5. At a minimum, emergency service medical records are kept for as long a time as required in a given State's statute of limitations.



Condition of Participation

XV. SOCIAL WORK DEPARTMENT

PARTICIPATION IS NOT LIMITED TO HOSPITALS WHICH HAVE SOCIAL WORK DEPARTMENTS, BUT IF THEY ARE PRESENT, THERE ARE EFFECTIVE POLICIES AND PROCEDURES RELATING TO THE STAFF AND THE FUNCTIONS OF THE SERVICE.

Standard A

The department is well organized and directed by a qualified medical social worker.

Factor 1. Preferably, social services are organized on a departmental level, responsible to the administration of the institution, and social workers in the institution are responsible to the department director, regardless of the unit to which they are assigned.

Factor 2. The social service staff includes social workers, social work assistants, and clerical personnel. The social workers are qualified by a master's degree from an accredited school of social work. The social work assistants are qualified by a bachelor's degree, preferably with a social welfare sequence, and are given training on the job for specific assignments and responsibilities.

Factor 3. The number of social workers and social work assistants is adequate to meet patient needs for patient care planning.

Factor 4. Planning for patient care includes participation by the social service department as indicated to enable the patient to make full use of inpatient, outpatient, or extended care or home health services in the community.

Standard B

The department is integrated with other departments of the hospital, and departmental and interdepartmental conferences are held periodically.

Factor 1. Department staff participate in ward rounds, medical staff seminars, nursing staff conferences, and in conferences with individual physicians and nurses concerned with the care of the patient.

Factor 2. The department communicates to appropriate administrative and professional personnel information on community programs and developments which may affect the hospital program.

Factor 3. The department participates in appropriate education, training, and orientation programs for nurses, medical students, interns and residents, and hospital administrative residents, as well as in inservice training programs.

Standard C

Records of social service activity related to individual patients are kept, and are available only to the professional personnel concerned.

Factor 1. Functions and activities recorded include:

(i) Medicosocial study of referred hospitalized and OPD patients; (ii) Evaluation of financial status of patient; (iii) Follow-up of discharged patients; (iv) Social therapy and rehabilitation of patients; (v) Environmental investigations for the attending physicians; and (vi) Cooperative activities with community agencies.

Factor 2. Significant social service summaries are entered promptly in the patient's central medical record for the benefit of all staff involved in care of the patient.

Factor 3. More detailed records are kept by the department to meet the needs of student or staff training, research, and review by supervisors or consultants.

Standard D

Facilities are provided which are adequate for the personnel of the department, easily accessible to patients and to the medical staff, and which assure privacy for interviews.



Condition of Participation

XVI. UTILIZATION REVIEW PLAN

THE HOSPITAL HAS IN EFFECT A PLAN FOR UTILIZATION REVIEW WHICH APPLIES AT LEAST TO THE SERVICES FURNISHED BY THE HOSPITAL TO INPATIENTS WHO ARE ENTITLED TO BENEFITS UNDER THE LAW. AN ACCEPTABLE UTILIZATION REVIEW PLAN PROVIDES FOR: (1) THE REVIEW, ON A SAMPLE OR OTHER BASIS, OF ADMISSIONS, DURATION OF STAYS, AND PROFESSIONAL SERVICES FURNISHED; AND (2) REVIEW OF EACH CASE OF CONTINUOUS EXTENDED DURATION.

Introduction

There are many types of plans which can fulfill the requirements of the law. Hospitals wishing to establish their eligibility to participate should submit a written description of their utilization review plan and a certification that it is currently in effect or that it will be in effect on July 1, 1966. Ordinarily this will constitute sufficient evidence to support a finding that the utilization review plan of the hospital is or is not in conformity with the statutory requirements. Intermediaries will be relied upon heavily to participate with the medical profession and the hospital administrative staff in long-run measures to assure that utilization review operates effectively.

The review plan of a hospital should have as its overall objective the maintenance of high quality patient care, and an increase in effective utilization of hospital services to be achieved through an educational approach involving study of patterns of care, and the encouragement of appropriate utilization. It is contemplated that a review of the medical necessity of admissions and durations of stay, for example, would take into account alternative use and availability of out-of-hospital facilities and services. The review of professional services furnished might include study of such conditions as overuse or underuse of services, logical substantiation of diagnoses, proper use of consultation, and whether required diagnostic workup and treatment are initiated and carried out promptly. Review of lengths of stay might consider not only medical necessity, but the effect that hospital staffing may have on duration of stay, whether assistance is available to the physician in arranging for discharge planning, and the availability of out-of-hospital facilities and services which will assure continuity of care.

Costs incurred in connection with the implementation of the utilization review plan are includable in

reasonable costs and are reimbursable to the hospital to the extent that such costs relate to health insurance program beneficiaries. For example, costs may include expenses incurred for the purchase of data from organizations outside the hospital which compile statistics, profiles, and study results on utilization of hospital facilities and services.

Standard A

The operation of the utilization review plan is a responsibility of the medical profession. The plan in the hospital has the approval of the medical staff as well as that of the governing body.

Standard B

The hospital has a currently applicable, written description of its utilization review plan. Such description includes:

- The organization and composition of the committee(s) which will be responsible for the utilization review function;
- Frequency of meetings;
- The type of records to be kept;
- The method to be used in selecting cases on a sample or other basis;
- The definition of what constitutes the period or periods of extended duration;
- The relationship of the utilization review plan to claims administration by a third party;
- Arrangements for committee reports and their dissemination;
- Responsibilities of the hospital's administrative staff.

Standard C

The utilization review function is conducted by one or a combination of the following:

- By a staff committee or committees of the hospital, each of which is composed of two or more

physicians, with or without the inclusion of other professional personnel; or

- By a committee(s) or group(s) outside the hospital composed as above which is established by the local medical society and some or all of the hospitals and extended care facilities in the locality; or
- Where a committee(s) or group(s) as described in the first or second paragraph of this standard has not been established to carry out all the utilization review functions prescribed by the Act, by a committee(s) or group(s) composed as in the first paragraph above, and sponsored and organized in such manner as approved by the Secretary of Health, Education, and Welfare.

Factor 1. The medical care appraisal and educational aspects of review on a sample or other basis, and the review of long-stay cases need not be done by the same committee or group.

Factor 2. Existing staff committees may assume the review responsibility stipulated in the plan. In smaller hospitals, all of these functions may be carried out by a committee of the whole or a medical care appraisal committee.

Factor 3. The committee(s) is broadly representative of the medical staff and at least one member does not have a direct financial interest in the hospital.

Standard D

Reviews are made, on a sample or other basis, of admissions, duration of stays, and professional services furnished, with respect to the medical necessity of the services, and for the purpose of promoting the most efficient use of available health facilities and services. Such reviews emphasize identification and analysis of patterns of patient care in order to maintain consistent high quality. The review is accomplished by considering data obtained by any one or any combination of the following:

- By use of services and facilities of external organizations which compile statistics, design profiles, and produce other comparative data; or
- By cooperative endeavor with the fiscal intermediary (ies) in the locality; or
- By internal studies of medical records.

Factor 1. Reviews of cases, based on diagnostic categories, include diagnoses of special relevance to the aged group.

Factor 2. Some review functions are carried out on a continuing basis.

Factor 3. Reviews include a sample of recertifications of medical necessity, as made for purposes of the Health Insurance for the Aged Program.

Standard E

Reviews are made of each beneficiary case of continuous extended duration. The hospital utilization review plan specifies the number of continuous days of hospital stay following which a review is made to determine whether further inpatient hospital services are medically necessary. The plan may specify a different number of days for different classes of cases. Reviews for such purpose are made no later than the seventh day following the last day of the period of extended duration specified in the plan. No physician has review responsibility for any extended stay cases in which he was professionally involved. If physician members of the committee decide, after opportunity for consultation is given the attending physician by the committee, and considering the availability and appropriateness of out-of-hospital facilities and services, that further inpatient stay is not medically necessary, there is notification in writing within 48 hours to the institution, the attending physician and the patient or his representative.

Factor 1. Because there are significant divergences in opinion among individual physicians in respect to evaluation of medical necessity for inpatient hospital services, the judgment of the attending physician in an extended stay case is given great weight, and is not rejected except under unusual circumstances.

Standard F

Records are kept of the activities of the committee; and reports are regularly made by the committee to the executive committee of the medical staff and relevant information and recommendations are reported through usual channels to the entire medical staff and the governing body of the hospital.

Factor 1. The hospital administration studies and acts upon administrative recommendations made by the committee.

Factor 2. A summary of the number and types of cases reviewed, and the findings, are part of the records.

Factor 3. Minutes of each committee meeting are maintained.

Factor 4. Committee action in extended stay cases is recorded, with cases identified only by hospital case number.

Standard G

The committee(s) having responsibility for utilization review functions have the support and assistance of the hospital's administrative staff in assembling information, facilitating chart reviews, conducting studies, exploring ways to improve procedures, maintaining committee records, and promoting the most efficient use of available health services and facilities.

Factor 1. With respect to each of these activities, an individual or department is designated as being responsible for the particular service.

Factor 2. In order to encourage the most efficient use of available health services and facilities, assistance to the physician in timely planning for post-hospital care is initiated as promptly as possible, either by hospital staff, or by arrangement with other agencies. For this purpose, the hospital makes available to the attending physician current information on resources available for continued out-of-hospital care of patients and arranges for prompt transfer of appropriate medical and nursing information in order to assure continuity of care upon discharge of a patient.



SPECIAL RULES AND EXCEPTIONS APPLYING TO PSYCHIATRIC AND TUBERCULOSIS HOSPITALS

The conditions of participation for psychiatric and tuberculosis hospitals are similar to those for other hospitals, though differing in some respects due to their different purposes. To provide assurance that the program while paying for active treatment in psychiatric and tuberculosis hospitals would avoid paying for care that is merely custodial, the conditions of participation require that the hospital be accredited by the Joint Commission on Accreditation of Hospitals, that its clinical records be sufficient to permit the Secretary to determine the degree and intensity of treatment furnished to beneficiaries, and that it meet staffing requirements the Secretary finds necessary for carrying out an active treatment program. A distinct part of an institution can be considered a psychiatric or a tuberculosis hospital if it meets the conditions even though the institution of which it is a part does not; and if the distinct

part meets requirements equivalent to the accreditation requirements of the JCAH, it could qualify under the program even though the institution is not accredited.

A distinct part of an institution will be considered to meet requirements equivalent to the accreditation requirements of the JCAH if it is found to be in substantial compliance with the Conditions of Participation I through XV.

In addition, psychiatric hospitals (or distinct parts thereof) must meet the requirements of section 1861(f) of the Social Security Act and be in substantial compliance with the Conditions of Participation XVII and XVIII, and tuberculosis hospitals (or distinct parts thereof) must meet the requirements of section 1861(g) of the Social Security Act and be in substantial compliance with the Conditions of Participation XIX and XX.



Condition of Participation

XVII. SPECIAL MEDICAL RECORD REQUIREMENTS FOR PSYCHIATRIC HOSPITALS

THE MEDICAL RECORDS MAINTAINED BY A PSYCHIATRIC HOSPITAL PERMIT DETERMINATION OF THE DEGREE AND INTENSITY OF THE TREATMENT PROVIDED TO INDIVIDUALS WHO ARE FURNISHED SERVICES IN THE INSTITUTION.

Standard A

Medical records stress the psychiatric components of the record including history of findings and treatment rendered for the psychiatric condition for which the patient is hospitalized.

Factor 1. The identification data includes the patient's legal status.

Factor 2. A provisional or admitting diagnosis is made on every patient at the time of admission and includes the diagnoses of intercurrent diseases as well as the psychiatric diagnoses.

Factor 3. The complaint of others regarding the patient is included as well as the patient's comments.

Factor 4. The psychiatric evaluation, including a medical history, contains a record of mental status and notes the onset of illness, the circumstances leading to admission, attitudes, behavior, estimate of intellectual functioning, memory functioning, orientation and an inventory of the patient's assets in descriptive, not interpretative, fashion.

Factor 5. A complete neurological examination is recorded at the time of the admission physical examination, when indicated.

Factor 6. The social service records, including reports of interviews with patients, family members and others, provide an assessment of home plans and family attitudes, and community resource contacts as well as a social history.

Factor 7. Reports of consultations, psychological evaluations, reports of electroencephalograms, dental records and reports of special studies are included in the record.

Factor 8. The individual comprehensive treatment plan is recorded, based on an inventory of the patient's

strengths as well as his disabilities, and includes a substantiated diagnosis in the terminology of the American Psychiatric Association's Diagnostic and Statistical Manual, short-term and long-range goals, and the specific treatment modalities utilized as well as the responsibilities of each member of the treatment team in such a manner that it provides adequate justification and documentation for the diagnoses and for the treatment and rehabilitation activities carried out.

Factor 9. The treatment received by the patient is documented in such a manner and with such frequency as to assure that all active therapeutic efforts such as individual and group psychotherapy, drug therapy, milieu therapy, occupational therapy, recreational therapy, industrial or work therapy, nursing care and other therapeutic interventions are included.

Factor 10. Progress notes are recorded by the physician, nurse, social worker and, when appropriate, others significantly involved in active treatment modalities. Their frequency is determined by the condition of the patient but should be recorded at least weekly for the first 2 months and at least once a month thereafter and should contain recommendations for revisions in the treatment plan as indicated as well as precise assessment of the patient's progress in accordance with the original or revised treatment plan.

Factor 11. The discharge summary includes a recapitulation of the patient's hospitalization and recommendations from appropriate services concerning follow-up or aftercare as well as a brief summary of the patient's condition on discharge.

Factor 12. The psychiatric diagnoses contained in the final diagnoses are written in the terminology of the American Psychiatric Association's Diagnostic and Statistical Manual.



Condition of Participation

XVIII. SPECIAL STAFF REQUIREMENTS FOR PSYCHIATRIC HOSPITALS

THE HOSPITAL HAS STAFF ADEQUATE IN NUMBER AND QUALIFICATIONS TO CARRY OUT AN ACTIVE PROGRAM OF TREATMENT FOR INDIVIDUALS WHO ARE FURNISHED SERVICES IN THE INSTITUTION.

Standard A

Inpatient psychiatric facilities (psychiatric hospitals, distinct parts of psychiatric hospitals or inpatient components of community mental health centers) are staffed with the number of qualified professional, technical and supporting personnel, and consultants required to carry out an intensive and comprehensive treatment program that includes evaluation of individual needs, establishment of treatment and rehabilitation goals, and implementation, directly or by arrangement, of a broad range therapeutic program including, at least, professional psychiatric, medical, surgical, nursing, social work, psychological and activity therapies as required to carry out an individual treatment plan for each patient.

Factor 1. Qualified professional, technical, and consultant personnel are available to evaluate each patient at the time of admission, including diagnosis of any intercurrent disease. Services necessary for such evaluation include laboratory, radiological and other diagnostic tests, obtaining psychosocial data, carrying out psychiatric and psychological evaluations, and completing a physical examination, including a complete neurological examination when indicated, shortly after admission.

Factor 2. The number of qualified professional personnel, including consultants and technical and supporting personnel, is adequate to assure representation of the disciplines necessary to establish short-range and long-term goals; and to plan, carry out, and periodically revise a written individualized treatment program for each patient based on scientific interpretation of:

(i) Degree of physical disability and indicated remedial or restorative measures, including nutrition, nursing, physical medicine, and pharmacological therapeutic interventions; (ii) Degree of psychological impairment and appropriate measures to be taken to relieve treatable distress and to compensate for non-reversible impairments where found; (iii) Capacity for social interaction and appropriate nursing measures

and milieu therapy to be undertaken, including group living experiences, occupational and recreational therapy, and other prescribed rehabilitative activities to maintain or increase the individual's capacity to manage activities of daily living; (iv) Environmental and physical limitations required to safeguard the individual's health and safety with a plan to compensate for these deficiencies and to develop the individual's potential for return to his own home, a foster home, an extended care facility, a community mental health center, or another alternative facility to full-time hospitalization.

Standard B

Inpatient psychiatric services are under the supervision of a clinical director, service chief or equivalent who is qualified to provide the leadership required for an intensive treatment program, and the number and qualifications of physicians are adequate to provide essential psychiatric services.

Factor 1. The clinical director, service chief or equivalent is certified by the American Board of Psychiatry and Neurology, or meets the training and experience requirements for examination by the Board ("Board eligible"). In the event the psychiatrist in charge of the clinical program is Board eligible, there is evidence of consultation given to the clinical program on a continuing basis from a psychiatrist certified by the American Board of Psychiatry and Neurology.

Factor 2. The medical staff is qualified legally, professionally and ethically for the positions to which they are appointed.

Factor 3. The number of physicians is commensurate with the size and scope of the treatment program.

Factor 4. Residency training is under the direction of a properly qualified psychiatrist.

Standard C

Physicians and other appropriate professional personnel are available at all times to provide necessary medical and surgical diagnostic and treatment services, including specialized services.

Factor 1. If medical and surgical diagnostic and treatment services are not available within the institution, qualified consultants or attending physicians are immediately available or a satisfactory arrangement has been established for transferring patients to a general hospital certified under the Health Insurance for the Aged Program.

Standard D

Nursing services are under the direct supervision of a registered professional nurse who is qualified by education and experience for the position; and the number of registered professional nurses, licensed practical nurses, and other nursing personnel are adequate to formulate and carry out the nursing components of the individual treatment plan for each patient.

Factor 1. The registered professional nurse supervising the nursing program has a master's degree in psychiatric or mental health nursing or its equivalent from a school of nursing accredited by the National League for Nursing, or is qualified by education, experience in the care of the mentally ill, and demonstrated competence to participate in interdisciplinary formulation of individual treatment plans; to give skilled nursing care and therapy; and to direct, supervise and train others who assist in implementing and carrying out the nursing components of each patient's treatment plan.

Factor 2. The staffing pattern insures the availability of a registered professional nurse 24 hours each day for direct care; for supervising care performed by other nursing personnel; and for assigning nursing care activities not requiring the services of a professional nurse to other nursing service personnel according to the patient's needs and the preparation and competence of the nursing staff available.

Factor 3. The number of registered professional nurses, including nurse consultants, is adequate to formulate in writing and assure that a nursing care plan for each patient is carried out.

Factor 4. Registered professional nurses and other nursing personnel are prepared by continuing in-service and staff development programs for active participation in interdisciplinary meetings affecting the planning or implementation of nursing care plans for patients including diagnostic conferences, treatment planning sessions, and meetings held to consider alternative facilities and community resources.

Standard E

The psychological services are under the supervision of a qualified psychologist and the psychology staff, including consultants, is adequate

in numbers and by qualifications to plan and carry out assigned responsibilities.

Factor 1. The psychology department or service is under the supervision of a psychologist with a doctoral degree in psychology from an American Psychological Association approved program in clinical psychology or its adjudged equivalent. Where a psychologist who does not hold the doctoral degree directs the program, he has attained recognition of competency through the American Board of Examinations for Professional Psychology, State certification or licensing, or through endorsement by his State psychological association.

Factor 2. Psychologists, consultants and supporting personnel are adequate in number and by qualifications to assist in essential diagnostic formulations, and to participate in program development and evaluation of program effectiveness, in training and research activities, in therapeutic interventions such as milieu, individual or group therapy, and in interdisciplinary conferences and meetings held to establish diagnoses, goals, and treatment programs.

Standard F

Social work services are under the supervision of a qualified social worker, and the social work staff is adequate in numbers and by qualifications to fulfill responsibilities related to the specific needs of individual patients and their families, the development of community resources, and consultation to other staff and community agencies.

Factor 1. The director of the social work department or service has a master's degree from an accredited school of social work and meets the experience requirements for certification by the National Association of Social Workers.

Factor 2. Social work staff, including other social workers, consultants and other assistants or case aides, is qualified and numerically adequate to conduct pre-hospitalization studies; to provide psychosocial data for diagnosis and treatment planning, direct therapeutic services to patients, patient groups or families, to develop community resources, including family or foster care programs; to conduct appropriate social work research and training activities; and to participate in interdisciplinary conferences and meetings concerning diagnostic formulation and treatment planning, including identification and utilization of other facilities and alternative forms of care and treatment.

Standard G

Qualified therapists, consultants, volunteers, assistants or aides are sufficient in number to provide comprehensive therapeutic activities, including at least occupational, recreational and

physical therapy, as needed, to assure that appropriate treatment is rendered for each patient, and to establish and maintain a therapeutic milieu.

Factor 1. Occupational therapy services are preferably under the supervision of a graduate of an occupational therapy program approved by the Council on Education of the American Medical Association who has passed or is eligible for the National Registration Examination of the American Occupational Therapy Association. In the absence of a full-time, fully qualified occupational therapist, an occupational therapy assistant who is certified by the American Occupational Therapy Association may function as the director of the activities program with consultation from a fully qualified occupational therapist.

Factor 2. If the hospital has an organized physical therapy department or service, the director is a graduate of a physical therapy program approved by the American Medical Association in collaboration with the American Physical Therapy Association. In the absence of a full-time, fully qualified physical therapist, physical therapy services are available by arrangement with a certified local hospital or by consultation

or part-time services furnished by a fully qualified physical therapist.

Factor 3. Recreational or activity therapy services are available under the direct supervision of a member of the staff who has demonstrated competence in therapeutic recreation programs.

Factor 4. Other occupational therapy, recreational therapy, activity therapy and physical therapy assistants or aides are directly responsible to qualified supervisors and are provided special on-the-job training to fulfill assigned functions.

Factor 5. The total number of occupational, recreational activity and rehabilitation personnel, including consultants, is sufficient to permit adequate representation and participation in interdisciplinary conferences and meetings affecting the planning and implementation of activity and rehabilitation programs, including diagnostic conferences; and to maintain all daily scheduled and prescribed activities including maintenance of appropriate progress records for individual patients.

Factor 6. Voluntary service workers are under the direction of a paid professional supervisor of volunteers, are provided appropriate orientation and training, and are available daily in sufficient numbers to be of assistance to patients and their families in support of therapeutic activities.



Condition of Participation

XIX. SPECIAL MEDICAL RECORD REQUIREMENTS FOR TUBERCULOSIS HOSPITALS

THE MEDICAL RECORDS MAINTAINED BY A TUBERCULOSIS HOSPITAL PERMIT DETERMINATION OF THE DEGREE AND INTENSITY OF THE TREATMENT PROVIDED TO INDIVIDUALS WHO ARE FURNISHED SERVICES IN THE INSTITUTION.

Standard A

The record contains reports on laboratory procedures undertaken to identify and characterize organisms, identify their drug susceptibility, protect the patient against potential drug toxicity, and measure pulmonary function.

Standard B

The record contains summaries of all scheduled case review conferences performed by the hospital staff, including as a minimum, summaries of case reviews performed upon initiation of therapy, within eight weeks after initiation of therapy, at least every three months thereafter, and prior to discharge.

Factor 1. A case review conference is a meeting of the medical staff of the hospital at which major medical decisions are made concerning the program of treatment for each patient. Other professional staff involved in the care of the patient participate in the review.

Factor 2. The summary of the case review conference includes: current diagnosis according to the National Tuberculosis Association's *Diagnostic Standards and Classification of Tuberculosis*, treatment, response to treatment, reference to X-ray and bacteriological findings, any special consultations, recommended schedule of future therapy, and prognosis.

Factor 3. The discharge summary contains a recapitulation of the significant findings and events of the patient's hospitalization including a listing of all drugs used and the reason for discontinuing each, the current diagnoses and medical status of the patient on discharge, and recommendations for follow-up including the kind and duration of post-hospitalization chemotherapy.

Standard C

Adequate progress notes contained in the record indicate response to therapy.

Factor 1. There is a note on the patient's condition, signed by a physician, at least once monthly.

Factor 2. Any change in treatment plan is indicated in the progress notes.



Condition of Participation

XX. SPECIAL STAFF REQUIREMENTS FOR TUBERCULOSIS HOSPITALS

THE HOSPITAL HAS STAFF ADEQUATE IN NUMBER AND QUALIFICATIONS TO CARRY OUT AN ACTIVE PROGRAM OF TREATMENT FOR INDIVIDUALS WHO ARE FURNISHED SERVICES IN THE INSTITUTION.

Standard A

There is a full-time medical director (or his equivalent) who has at least 3 years experience in chest diseases or is Board eligible or Board certified in internal medicine, and who is well versed in the various aspects of tuberculosis.

Factor 1. The medical director is responsible for the medical affairs in the hospital. If he is also responsible for the non-medical affairs of the hospital, he has an administrator or business manager to administer these affairs.

Factor 2. If the medical director carries a patient load in addition to supervising the conduct of medical affairs in the hospital, this additional responsibility does not interfere with his duties as director.

Standard B

There is a sufficient number of qualified physicians on the medical staff to provide medical supervision and active treatment for each tuberculous patient.

Factor 1. Physicians are legally qualified and have the professional skills necessary to care for tuberculous patients.

Factor 2. Active treatment includes:

(i) Initial evaluation at a staff case review conference; (ii) A planned regimen of specific antituberculous measures including chemotherapy, designed to render the disease non-communicable and to improve the patient's condition so that he may safely return to his community for continued supervision and treatment; and (iii) Periodic assessment of progress at case review conferences.

Factor 3. It is preferable that staff physicians be full-time. If full-time staff cannot be obtained, the services of regularly scheduled part-time physicians may be used in order to provide needed services. This does not preclude the hospital from continuing efforts to obtain sufficient full-time staff.

Factor 4. One or more physicians are on duty at all times.

Standard C

The services of a thoracic surgeon, as a member of the medical team responsible for treating the tuberculous patient, are available on a regularly scheduled basis and for emergencies.

Factor 1. The thoracic surgeon is either Board certified or eligible for Board certification in thoracic surgery.

Factor 2. In addition to his regular visits to the hospital for examination of selected patients, he attends case review conferences as a member of the medical team responsible for the care of the tuberculous patient.

Factor 3. He is either on the full-time hospital staff or is available under arrangements with the hospital to provide specified consultative and surgical services. Necessary surgical procedures may be performed in another hospital.

Standard D

Consultative services in other medical and surgical specialties are available to meet the total medical needs of the patients.

Factor 1. Specialists in areas such as urology and orthopedic surgery are available to assist the staff through consultation and, if necessary, direct service in handling complications of tuberculosis.

Factor 2. Specialists in other fields are available to assist as necessary in the treatment of additional medical disorders of the patients.

Standard E

Qualified personnel are available to provide mental health consultation and guidance to the staff, and such direct patient service as is appropriate to give in the tuberculosis hospital.

Factor 1. If mental health services are not available from hospital staff, arrangements are made for these services with outside agencies or institutions.

Factor 2. Mental health consultation and guidance, including guidance with respect to the alcoholic patient,

are provided to the staff by qualified mental health personnel such as psychiatrists and/or psychologists.

Factor 3. Patients with severe mental disturbances have ready access to the services of a qualified psychiatrist.

Standard F

A staff person is responsible for direction and supervision of activities related to the social needs of all patients, and to the mobilization and use of community resources to meet these needs. The number of professional personnel and non-professional social work assistants is sufficient to meet the institution's requirements.

Factor 1. Preferably, social work direction and supervision are by a qualified social worker with a master's degree from an accredited school of social work and related professional experience.

Factor 2. If the hospital does not have a qualified social worker on the staff, arrangements are made with another agency for overall direction and continuing supervision of hospital social services by a qualified social worker.

Factor 3. The director of the service assigns responsibilities related to the specific needs of individual patients to professional social workers or to non-professional social work assistants according to their ability or training. Non-professional social work assistants receive in-service training to enable them to perform assigned functions.

Factor 4. A social worker familiar with the patient's social needs participates in the case review conference.

Factor 5. The social service staff effectively uses available community resources to assist in providing needed services to the patient and his family, and is responsible for proper community referrals upon discharge from the hospital.

Standard G

A staff person is responsible for arranging for patients appropriate diversionary and recrea-

tional activities as an important adjunct to the active treatment program.

Factor 1. Preferably, these activities are under the direction of an occupational therapist who is registered by the American Occupational Therapy Association.

Factor 2. Assistants, aides, or volunteers providing these services are directly responsible to a qualified person on the staff and are provided on-the-job training.

Standard H

There is a person with major responsibility for liaison between the hospital and, in the community in which the patient is to be supervised and treated upon discharge, the official health agency responsible for tuberculosis control and any other agencies or individuals who will be involved in the patient's treatment and follow-up.

Factor 1. This person may be an employee of the hospital or an employee of an outside health agency assigned to the hospital for this purpose.

Factor 2. This person is responsible for the administration of a written policy establishing effective lines of communication between the hospital and the official health agency responsible for tuberculosis control in the community and other agencies or individuals who will be involved in the patient's treatment and follow-up.

Factor 3. The policy includes procedures for:

(i) Informing the official health agency of the admission of the patient to the hospital and of the anticipated return of the patient to the community either on discharge or leave from the hospital; (ii) Assisting the local health agency in obtaining information from the patient on sources of infection and contacts that may have public health significance; (iii) Transferring to the official health agency and any other agencies or individuals involved in the patient's treatment and follow-up medical and related information as needed to insure continuity and effectiveness of medical care.

APPENDIX A

Excerpts from Public Law 89-97

The following excerpts define hospitals, tuberculosis hospitals, psychiatric hospitals, utilization review, and explain the effect of accreditation.

Section 1861. (c) The term "hospital" (except for purposes of section 1814(d), subsection (a) (2) of this section, paragraph (7) of this subsection, and subsections (i) and (n) of this section) means an institution which—

(1) is primarily engaged in providing, by or under the supervision of physicians, to inpatients (a) diagnostic services and therapeutic services for medical diagnosis, treatment, and care of injured, disabled, or sick persons, or (B) rehabilitation services for the rehabilitation of injured, disabled, or sick persons;

(2) maintains clinical records on all patients;

(3) has bylaws in effect with respect to its staff of physicians;

(4) has a requirement that every patient must be under the care of a physician;

(5) provides 24-hour nursing service rendered or supervised by a registered professional nurse, and has a licensed practical nurse or registered professional nurse on duty at all times;

(6) has in effect a hospital utilization review plan which meets the requirements of subsection (k);

(7) in the case of an institution in any State in which State or applicable local law provides for the licensing of hospitals, (A) is licensed pursuant to such law or (B) is approved, by the agency of such State or locality responsible for licensing hospitals, as meeting the standards established for such licensing; and

(8) meets such other requirements as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in the institution, except that such other requirements may not be higher than the comparable requirements prescribed for the accreditation of hospitals by the Joint Commission on Accreditation of Hospitals.

For purposes of subsection (a) (2), such term includes any institution which meets the requirements of paragraph (1) of this subsection. For purposes of sections 1814(d) (including determination of whether an individual received inpatient hospital services for purposes of such section), and subsections (i) and (n)

of this section, such term includes any institution which meets the requirements of paragraphs (1), (2), (3), (4), (5), and (7) of this subsection. Notwithstanding the preceding provisions of this subsection, such term shall not, except for purposes of subsection (a) (2), include any institution which is primarily for the care and treatment of mental diseases or tuberculosis unless it is a tuberculosis hospital (as defined in subsection (g)) or unless it is a psychiatric hospital (as defined in subsection (f)). The term "hospital" also includes a Christian Science sanatorium operated, or listed and certified, by the First Church of Christ, Scientist, Boston, Massachusetts, but only with respect to items and services ordinarily furnished by such institution to inpatients, and payment may be made with respect to services provided by or in such an institution only to such extent and under such conditions, limitations, and requirements (in addition to or in lieu of the conditions, limitations, and requirements otherwise applicable) as may be provided in regulations. For provisions deeming certain requirements of this subsection to be met in the case of accredited institutions, see section 1865.

Section 1861. (f) The term "psychiatric hospital" means an institution which—

(1) is primarily engaged in providing, by or under the supervision of a physician, psychiatric services for the diagnosis and treatment of mentally ill persons;

(2) satisfies the requirements of paragraphs (3) through (8) of subsection (e);

(3) maintains clinical records on all patients and maintains such records as the Secretary finds to be necessary to determine the degree and intensity of the treatment provided to individuals entitled to hospital insurance benefits under part A;

(4) meets such staffing requirements as the Secretary finds necessary for the institution to carry out an active program of treatment for individuals who are furnished services in the institution; and

(5) is accredited by the Joint Commission on Accreditation of Hospitals.

In the case of an institution which satisfies paragraphs (1) and (2) of the preceding sentence and which contains a distinct part which also satisfies paragraphs (3) and (4) of such sentence, such distinct part shall be considered to be a 'psychiatric hospital' if the institution is accredited by the Joint Commission on Accreditation of Hospitals or if such distinct part meets requirements equivalent to such accreditation requirements as determined by the Secretary.

Section 1861. (g) The term "tuberculosis hospital" means an institution which—

(1) is primarily engaged in providing, by or under the supervision of a physician, medical services for the diagnosis and treatment of tuberculosis;

(2) satisfies the requirements of paragraphs (3) through (8) of subsection (e);

(3) maintains clinical records on all patients and maintains such records as the Secretary finds to be necessary to determine the degree and intensity of the treatment provided to individuals covered by the insurance program established by part A;

(4) meets such staffing requirements as the Secretary finds necessary for the institution to carry out an active program of treatment for individuals who are furnished services in the institution; and

(5) is accredited by the Joint Commission on Accreditation of Hospitals.

In the case of an institution which satisfies paragraphs (1) and (2) of the preceding sentence and which contains a distinct part which also satisfies paragraphs (3) and (4) of such sentence, such distinct part shall be considered to be a 'tuberculosis hospital' if the institution is accredited by the Joint Commission on Accreditation of Hospitals or if such distinct part meets requirements equivalent to such accreditation requirements as determined by the Secretary.

Section 1861. (k) A utilization review plan of a hospital or extended care facility shall be considered sufficient if it is applicable to services furnished by the institution to individuals entitled to insurance benefits under this title and if it provides—

(1) for the review, on a sample or other basis, of admissions to the institution, the duration of stays therein, and the professional services (including drugs and biologicals) furnished, (A) with respect to the medical necessity of the services, and (B) for the purpose of promoting the most efficient use of available health facilities and services;

(2) for such review to be made by either (A) a staff committee of the institution composed of two or more physicians, with or without participation of other professional personnel, or (B) a group outside the institution which is similarly composed and (i) which is established by the local medical society and some or all of the

hospitals and extended care facilities in the locality, or (ii) if (and for as long as) there has not been established such a group which serves such institution, which is established in such other manner as may be approved by the Secretary.

(3) for such review, in each case of inpatient hospital services or extended care services furnished to such an individual during a continuous period of extended duration, as of such days of such period (which may differ for different classes of cases) as may be specified in regulations, with such review to be made as promptly as possible, after each day so specified, and in no event later than one week following such day; and

(4) for prompt notification to the institution, the individual, and his attending physician of any finding (made after opportunity for consultation to such attending physician) by the physician members of such committee or group that any further stay in the institution is not medically necessary.

The review committee must be composed as provided in clause (B) of paragraph (2) rather than as provided in clause (A) of such paragraph in the case of any hospital or extended care facility where, because of the small size of the institution, or (in the case of an extended care facility) because of lack of an organized medical staff, or for such other reason or reasons as may be included in regulations, it is impracticable for the institution to have a properly functioning staff committee for the purposes of this subsection.

Section 1863. In carrying out his functions, relating to determination of conditions of participation by providers of services, under subsections (e) (8), (f) (4), (g) (4), (j) (10), and (o) (5) of section 1861, the Secretary shall consult with the Health Insurance Benefits Advisory Council established by section 1867, appropriate State agencies, and recognized national listing or accrediting bodies, and may consult with appropriate local agencies. Such conditions prescribed under any of such subsections may be varied for different areas or different classes of institutions or agencies and may, at the request of a State, provide higher requirements for such State than for other States; except that, in the case of any State or political subdivision of a State which imposes higher requirements on institutions as a condition to the purchase of services (or of certain specified services) in such institutions under a State plan approved under title I, XVI, or XIX, the Secretary shall impose like requirements as a condition to the payment for services (or for the services specified by the State or subdivision) in such institutions in such State or subdivision.

Section 1865. An institution shall be deemed to meet the requirements of the numbered paragraphs of section 1861(e) (except paragraph (6) thereof) if

such institution is accredited as a hospital by the Joint Commission on Accreditation of Hospitals. If such Commission, as a condition for accreditation of a hospital, requires a utilization review plan or imposes another requirement which serves substantially the same purpose, the Secretary is authorized to find that all institutions so accredited by the Commission comply also with section 1861(e)(6). In addition, if the

Secretary finds that accreditation of an institution or agency by the American Osteopathic Association or any other national accreditation body provides reasonable assurance that any or all of the conditions of section 1861 (e), (j), or (o), as the case may be, are met, he may, to the extent he deems it appropriate, treat such institution or agency as meeting the condition or conditions with respect to which he made such finding.



APPENDIX B

Hospital Request to Establish Eligibility in the Health Insurance for the Aged Program

Instructions for Completing the Form





HOSPITAL REQUEST TO ESTABLISH ELIGIBILITY IN THE HEALTH INSURANCE FOR THE AGED PROGRAM

Form approved,
Budget Bureau No. 72-R717

DO NOT WRITE IN THIS SPACE

ID

S/C

SMSA

DO

DATE CERTIFIED

CERTIFICATION

All hospitals desiring to establish their eligibility in the health insurance program should complete this form and return it to the State agency that is handling the certification process. If a return envelope is not provided, the name and address of the State agency may be obtained from the nearest Social Security Administration district office.

Hospitals accredited by the Joint Commission on Accreditation of Hospitals will be considered to meet all of the Conditions for Participation in the program, except that of having a utilization review plan.

SUBMISSION OF THIS FORM AND ESTABLISHING ELIGIBILITY DOES NOT OBLIGATE A HOSPITAL TO PARTICIPATE. AN AGREEMENT WILL BE MADE AVAILABLE BY THE SOCIAL SECURITY ADMINISTRATION AT A LATER DATE TO HOSPITALS WHO HAVE ESTABLISHED ELIGIBILITY. THERE IS NO COMMITMENT UNTIL THE AGREEMENT IS SIGNED.

I. Identifying Information	NAME OF HOSPITAL		STREET ADDRESS	
	CITY, COUNTY, AND STATE		ZIP CODE	TELEPHONE NUMBER (including area code)
	NAME OF CHIEF ADMINISTRATIVE OFFICER		TITLE	
	NAME AND ADDRESS OF PARENT INSTITUTION (If applicable)			
II. Licensure	1 <input type="checkbox"/> Licensed or approved as a hospital by a state or local Government Agency NAME OF AGENCY		LICENSE EFFECTIVE BEGINNING DATE THRU DATE	
			2 <input type="checkbox"/> No license or approval required	
III. JCAH Accreditation	1 <input type="checkbox"/> THREE YEAR BEGINNING DATE THRU DATE		2 <input type="checkbox"/> ONE YEAR BEGINNING DATE THRU DATE	
	3 <input type="checkbox"/> NOT ACCREDITED a. <input type="checkbox"/> Accreditation Pending b. <input type="checkbox"/> Refused <input type="checkbox"/> Never Applied			
IV. Utilization Review Plan	A. Does the hospital have a Utilization Review Plan in effect at present?		1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No	
	B. If "Yes," Utilization Review to be made by: 1 <input type="checkbox"/> Committee(s) of Hospital Medical Staff 2 <input type="checkbox"/> Group outside the Hospital established by Local Medical Society 3 <input type="checkbox"/> Other			
PLEASE ATTACH A COPY OR TENTATIVE DESCRIPTION OF YOUR UTILIZATION REVIEW PLAN, IF AVAILABLE.				
V. Nursing	Does the hospital provide 24-hour nursing service rendered or supervised by a registered professional nurse and is a licensed practical nurse or a registered professional nurse on duty at all times?			
	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No			
VI. By-Laws	Does the hospital have by-laws in effect with respect to its staff of physicians?			
	1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No			

VII. Type of Hospital (Check one that most accurately describes)		ITEMS VII THRU XIII ARE FOR STATISTICAL PURPOSES		
		1 <input type="checkbox"/> General—Short Term	4 <input type="checkbox"/> Psychiatric	7 <input type="checkbox"/> Specialty—Long Term
		2 <input type="checkbox"/> General—Long Term	5 <input type="checkbox"/> Chronic Disease	8 <input type="checkbox"/> Other (Specify)
		3 <input type="checkbox"/> Tuberculosis	6 <input type="checkbox"/> Specialty—Short Term	
VIII. Type of Control (Check one)		Voluntary Non-Profit 1 <input type="checkbox"/> Church 2 <input type="checkbox"/> Other (Specify) _____ Proprietary 3 <input type="checkbox"/>		
		Government (Non-Federal)	4 <input type="checkbox"/> State 5 <input type="checkbox"/> County 6 <input type="checkbox"/> City 7 <input type="checkbox"/> City—County 8 <input type="checkbox"/> Hospital District 9 <input type="checkbox"/> Specify Agency _____	
IX. Facilities and Services Available on the Premises (Check all applicable)		01 <input type="checkbox"/> Blood Bank 02 <input type="checkbox"/> Clinical Laboratory 03 <input type="checkbox"/> Pathology Laboratory 04 <input type="checkbox"/> Electrocardiograph 05 <input type="checkbox"/> Electroencephalograph 06 <input type="checkbox"/> Pharmacy 07 <input type="checkbox"/> Occupational Therapy Dept. 08 <input type="checkbox"/> Physical Therapy Dept. 09 <input type="checkbox"/> Intensive Care Unit 10 <input type="checkbox"/> Organized Outpatient Dept. 11 <input type="checkbox"/> Emergency Department 12 <input type="checkbox"/> Home Care Program 13 <input type="checkbox"/> Operating Room 14 <input type="checkbox"/> Post-Operative Recovery Room 15 <input type="checkbox"/> Medical Social Service Dept. 16 <input type="checkbox"/> X-Ray, Diagnostic 17 <input type="checkbox"/> X-Ray, Therapeutic 18 <input type="checkbox"/> Radioactive Isotope Facility 19 <input type="checkbox"/> Psychiatric Inpatient Care Unit 20 <input type="checkbox"/> Cobalt and Radium Therapy 21 <input type="checkbox"/> Rehabilitation Unit 22 <input type="checkbox"/> Extended Care Unit 23 <input type="checkbox"/> Other (Specify) _____		
X. Bed Capacity		TOTAL ADULT BEDS		
XI. Number of Medical Staff Members		A. ACTIVE	B. CONSULTING	C. HONORARY
		D. ASSOCIATE	E. COURTESY	F. INTERNS-IN-TRAINING
		G. RESIDENTS-IN-TRAINING	H. OTHER	
XII. Number of Employees (Full Time Equivalents)		A. REGISTERED PROFESSIONAL NURSES	B. LICENSED PRACTICAL NURSES	C. REGISTERED PHARMACISTS
		D. REGISTERED OCCUPATIONAL THERAPISTS	E. QUALIFIED PHYSICAL THERAPISTS	F. QUALIFIED MEDICAL SOCIAL WORKERS
		G. OTHER SOCIAL WORK PERSONNEL	H. ALL OTHERS	
XIII. Training Programs		A. AFFILIATED WITH A MEDICAL SCHOOL 1 <input type="checkbox"/> Major 2 <input type="checkbox"/> Limited 3 <input type="checkbox"/> Graduate 4 <input type="checkbox"/> No Affiliation	B. INTERN PROGRAM APPROVED BY: 1 <input type="checkbox"/> American Medical Association 2 <input type="checkbox"/> American Dental Association 3 <input type="checkbox"/> American Osteopathic Association 4 <input type="checkbox"/> No Intern Program	C. NUMBER OF RESIDENT PROGRAMS APPROVED BY: 1 <input type="checkbox"/> American Medical Association 2 <input type="checkbox"/> American Osteopathic Association 3 <input type="checkbox"/> American Dental Association 4 <input type="checkbox"/> Check if No Resident Program
XIV. Non-Discrimination		A. The regulation of the Department of Health, Education and Welfare issued under the authority of Title VI of the Civil Rights Act of 1964 requires every institution receiving financial assistance under any program administered by the Department to file an assurance of its compliance with the requirements of such regulation. The hospital insurance benefits program under Part A of Title XVIII of the Social Security Act is one of the programs which is covered by Title VI of the Civil Rights Act and to which the regulation is applicable. Have you already evaluated the availability of your services, your admission and room assignment practices, your practices in the granting of staff privileges, and your training programs (if any), and satisfied yourself that they are in compliance with the requirements of Title VI of the Civil Rights Act of 1964 and the applicable Federal Regulations? 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No B. Have you filed with any Federal or State agency an assurance of compliance with these requirements? 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No If "Yes," name of agency _____		
SIGNATURE OF AUTHORIZED OFFICIAL		TITLE		DATE

INSTRUCTIONS FOR COMPLETING HOSPITAL REQUEST TO ESTABLISH ELIGIBILITY IN THE HEALTH INSURANCE FOR THE AGED PROGRAM (SSA 1514)

Hospitals accredited by the Joint Commission on Accreditation of Hospitals may establish their eligibility to provide services for reimbursement under the program by submitting to the designated State agency information on this form, and a utilization review plan meeting the requirements of the law. For other hospitals, the filing of this request for eligibility will initiate the process of obtaining a decision as to whether the conditions of participation are met. A hospital that establishes its eligibility may later enter into an agreement to become a participating hospital.

Submission of this form and establishing eligibility does not obligate a hospital to participate. An agreement will be made available by the Social Security Administration at a later date to hospitals who have established eligibility. There is no commitment until the agreement is signed.

Please do not delay returning the form even though certain information is not now available (e.g., the utilization review plan has not been completed). Assistance in filling out the form is available from the State agency.

General Instructions

Please answer all questions as of the current date.

Return the original and first copy to the State agency in the envelope provided; retain the second copy for your files. If a return envelope is not provided, the name and address of the State agency may be obtained from the nearest Social Security Administration district office.

A psychiatric or tuberculosis hospital that has its own hospital administration and maintains separate fiscal records, although it is part of a medical center or other large complex, should file a separate request. Psychiatric or tuberculosis wings of general hospitals should not file a separate request.

If the hospital has a home care program and/or an extended care unit, separate requests (SSA 1515 and SSA 1516, respectively) must be filed for such facilities for participation in the program. These forms will be made available in the near future.

Detailed Instructions for Specific Questions

These instructions are designed to clarify certain questions on the form. Instructions are listed in ques-

tion order, for easy reference. No instructions have been given for questions considered self-explanatory.

Question III—JCAH Accreditation

If not accredited, check 3 and also check one of the three boxes, accreditation pending, refused, or never applied.

Question IV—Utilization Review Plan

DO NOT DELAY SENDING YOUR REQUEST TO THE STATE AGENCY IF YOU DO *NOT* HAVE A UTILIZATION REVIEW PLAN. It is recognized that some hospitals may require additional time or may need to seek consultation from their fiscal intermediary and/or the State agency. The hospital should arrange to complete its utilization review plan as far in advance of July 1, 1966, as is possible. The State agency will be glad to consult with you concerning the timing and method of fulfilling this requirement. Your utilization review plan should comply with the requirements for utilization review as stated in the conditions of participation for hospitals.

Question VII—Type of Hospital

Check the one category most descriptive of your hospital's predominant type of care. "Short term" means average patient stay under 30 days; "long term" means average patient stay 30 days or over. Where primarily a specialty hospital other than tuberculosis, psychiatric, or chronic disease, check "specialty—short term" or "specialty—long term."

Question VIII—Type of Control

Check the one category that is most descriptive of the type of organization operating the hospital.

Question X—Bed Capacity

Indicate number of beds regularly available (those set up and staffed for use). Hospitals which are units of non-hospital institutions, (e.g., homes for the aged) or hospitals which have an extended care unit should report for the hospital unit only. Generally, the following should serve as a guide to inclusions and exclusions. *Include:* Isolation units, quiet rooms, reception

and observation units or any other such bed facilities which are set up and staffed for use by inpatients who have no other bed facility assigned to or reserved for them. *Exclude:* (1) bassinets and pediatric beds; (2) facilities which are set up and staffed only for patients receiving special procedures for a portion of their stay, or which are used only as holding facilities prior to transfer by the patient to another hospital (e.g., labor rooms, postanesthesia or postoperative recovery room beds, or psychiatric holding beds).

Question XII—Number of Employees

Include only those personnel regularly employed. Include members of religious orders. Exclude all trainees, private-duty nurses, and volunteers. To arrive at full-time equivalents, add the total number of hours worked by all employees in each classification in the week ending prior to the week of filing the request and divide by the number of hours in the standard workweek. If the result for each classification is not a whole number, express it as a fraction (e.g., $2\frac{1}{4}$).

Include in the count of *qualified physical therapists* only those physical therapists who are graduates of a program in physical therapy approved by the Council on Education of the American Medical Association or its equivalent.

Include in the count of *qualified medical social workers* only those medical social workers who have a master's degree from an accredited school of social work or who are members of the National Association of Social Workers.

Question XIII—Training Programs

In answering part A, check the box showing the hospital's affiliation as shown in the *Consolidated List of*

Hospitals With Approved Graduate Training Programs in the American Medical Association "Directory of Approved Internships and Residencies."

In answering part C, enter for 1, 2, and 3 the actual number of approved resident programs. If no approved resident program, check item 4.

Question XIV—Nondiscrimination

The regulation of the Department of Health, Education, and Welfare issued under the authority of title VI of the Civil Rights Act of 1964 requires every institution receiving financial assistance under any program administered by the Department to file an assurance of its compliance with the requirements of such regulation. Eligible hospitals desiring to participate in the hospital insurance benefits program under part A of title XVIII of the Social Security Act will be required, as part of their agreement to participate, to comply with title VI of the Civil Rights Act of 1964.

Assurance of compliance under title VI of the Civil Rights Act of 1964 is required for many programs; e.g., Federal assistance payments under the Hill-Burton program and for the receipt of medical care payments under welfare programs.

Check Yes to part B of the question and indicate the name of the agency if you have filed a compliance statement form with any Federal agency (e.g., Department of Health, Education, and Welfare; Department of Defense; Department of Agriculture; Atomic Energy Commission; etc.). Also check Yes if you have filed a compliance statement (or its equivalent) with a State agency or have agreed on a voucher form, authorization form, etc., to comply with title VI of the Civil Rights Act of 1964.



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**CONDITIONS
OF PARTICIPATION
FOR HOME HEALTH
AGENCIES**

U.S. Bureau of Health Insurance



U.S. DEPARTMENT OF
HEALTH, EDUCATION, AND WELFARE
SOCIAL SECURITY ADMINISTRATION

HIM-2 (3-66)



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APPENDIX A

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APPENDIX B

Home Health Agency Request to Establish Eligibility in the Health Insurance for the Aged Program

Instructions for Completing the Form

INTRODUCTION

In order to participate as a home health agency in the health insurance program for the aged, an institution must be a "home health agency" within the meaning of Section 1861(o) of the Social Security Act. This section of the law states a number of specific requirements which must be met by participating home health agencies and authorizes the Secretary of Health, Education, and Welfare to prescribe other requirements considered necessary in the interest of health and safety of beneficiaries. The requirements included in the statute and the additional health and safety requirements to be prescribed by the Secretary are incorporated into the Conditions of Participation for Home Health Agencies.

The following are examples of agencies which might be eligible for participation in the health insurance program:

Visiting nurse association

Subdivision of a local or State health department

Combination visiting nurse association-Health Department Agency

Subdivision of a local or State welfare department offering home health services

Department of a hospital, medical school, medical clinic, extended care facility or rehabilitation facility offering home health services

The Conditions of Participation for Home Health Agencies and related policies, as set forth herein will be reflected in regulations of the Department of Health, Education, and Welfare. Meanwhile, the Social Security Administration is making the conditions available to home health agencies as well as to State agencies and other organizations involved in the process of establishing the qualifications of home health agencies in order that interested home health agencies may apply for a determination of their eligibility to participate in the health insurance program. The law makes provision for the designation of State health agencies, or other State agencies, to assist the Department in determining whether the conditions of participation have been met. The

designated State agencies will certify to the Department of Health, Education, and Welfare home health agencies which meet the conditions, and will provide consultation to home health agencies to assist them to qualify. A home health agency which meets all of the specific statutory requirements and is found to be in substantial compliance with the conditions prescribed in regulations may, if it so desires, agree to become a participating home health agency.

The conditions of participation have been developed in accordance with the requirements, authorizations and limitations of the law.¹ Concurrently with the release of these materials to interested individuals, organizations, and agencies, the Department of Health, Education, and Welfare will proceed with the necessary action to establish conforming regulations. The official Notice of Proposed Rule Making and notice of the opportunity for submission of data, comments, and arguments relating to the proposed regulations are being provided in accordance with the regular procedure of publication in the Federal Register.

Conditions of Participation

In the preparation of the conditions of participation, there has been extensive discussion and consultation with organizations and experts in the medical, nursing, and related fields. Groups consulted included representatives of State health and welfare departments, the American Hospital Association, the American Medical Association, the American Nurses' Association, the National League for Nursing, and the Association of State and Territorial Health Officers, among others. The conditions of participation have also been reviewed and endorsed

¹ The law provides that the Secretary may, at the request of a State, approve higher health and safety requirements for that State than are reflected in the Conditions of Participation for Home Health Agencies; and where a State or political subdivision imposes higher requirements on home health agencies as a condition for the purchase of services under a State plan approved under Title I, XVI, or XIX of the Social Security Act, the Secretary is required to impose like requirements as a condition to the payment for services by the home health agencies in that State or subdivision.

by the Health Insurance Benefits Advisory Council, the statutory body established for the purpose of advising the Secretary on matters of general policy in the administration of this program and in the formulation of applicable regulations.

For a home health agency to be eligible for participation in the program, it must meet the specific statutory requirements of Section 1861(o) as well as the additional conditions established in the interest of health and safety which are essential to the maintenance of quality of care and the adequacy of the services which the agency provides. It will not be unusual for home health agencies to differ in the manner in which these conditions will be met. Variations in the type and size of agencies and the nature and scope of services offered will be reflected in differences in the details of organization and staffing. *However, the test will be whether there is substantial compliance with each of the conditions.*

As a basis for a determination as to whether or not there is substantial compliance with the prescribed conditions in the case of any particular home health agency, explanations are given under each condition. These explanations provide an indication of the various ways in which such agencies may carry out the functions embodied in the conditions. Reference to these explanations will enable the State agency surveying a home health agency to document the activities of the agency, to establish the nature and extent of its deficiencies, if any, with respect to any particular function, and to assess the agency's need for improvement in relation to the prescribed conditions. In substance, the explanations will help the State agency determine the extent and degree to which a home health agency is complying with each condition.

Procedures for Establishing Eligibility To Participate

The Health Insurance for the Aged Act provides that the State agencies, operating under agreements with the Department, will be used by the Department in determining whether institutions meet the conditions of participation. Pursuant to these agreements, State agencies will certify to the Department findings as to whether home health agencies are in substantial compliance with the conditions. Such certifications will include findings as to whether each of the conditions is substantially met. The Department, on the basis of such certi-

fication from the State agency, will determine whether or not an entity is a home health agency eligible to participate in the health insurance program as a provider of services.

The decisions of the State agency represent recommendations to the Secretary. Notice of determination of eligibility or non-eligibility made by the Department on the basis of a State agency decision will be sent to the home health agency by the Social Security Administration after such review and professional consultation with the Public Health Service as may be required. If it is determined that the home health agency does not comply with the conditions of participation, the home health agency has a right to appeal the determination and request a hearing. If the final decision which a home health agency receives after an appeal is unfavorable, it may request judicial review by the Federal Courts.

The appendix of this pamphlet contains samples of the form and instructions which will be made available by State agencies to home health agencies and which will be used to initiate the process of establishing eligibility. In addition to utilizing information available in licensure or other files, State agencies will conduct such surveys as may be necessary to determine the degree to which the conditions are met. A home health agency may obtain further information or assistance from the designated State agency or from the Regional Representative, Bureau of Health Insurance, Social Security Administration. The address of the designated State agency or the regional office can be secured from any district office of the Social Security Administration.

Principles for the Evaluation of Home Health Agencies To Determine Whether They Are in Substantial Compliance With the Conditions of Participation

Home health agencies will be considered in substantial compliance with the conditions of participation upon acceptance by the Secretary of findings, adequately documented and certified to by the State agency, showing that:

- A. The home health agency meets the specific statutory requirements² of Section 1861(o) and is found to be operating in accordance with all

² Statutory requirements incorporated in the conditions of participation are indicated by italics.

conditions of participation with no significant deficiencies, or

B. The home health agency meets the specific statutory requirements of Section 1861(a) but is found to have deficiencies with respect to one or more conditions of participation which:

1. It is making reasonable plans and efforts to correct, and
2. Notwithstanding the deficiencies, is rendering adequate care and without hazard to the health and safety of individuals being served, taking into account special procedures or precautionary measures which have been or are being instituted.

Time Limitations on Certifications of Substantial Compliance

All initial certifications by the State agency to the effect that a home health agency is in substantial compliance with the conditions of participation will be for a period of two years, beginning with July 1, 1966, or, if later, with the date on which the home health agency is first found to be in substantial compliance with the conditions. State agencies may visit or resurvey home health agencies where necessary to ascertain continued compliance or to accommodate to periodic or cyclical survey programs. A State finding and certification to the Secretary that an agency is no longer in compliance (see next topic) may occur within a two-year or subsequent period of certification and will terminate the State certification as to compliance.

If a home health agency is certified by the State agency as in substantial compliance under the provisions of Paragraph B., above, the following information will be incorporated into the finding and into the notice of eligibility to the home health agency:

- A. A statement of the deficiencies which were found, and
- B. A description of progress which has been made and further action which is being taken to remove the deficiencies, and
- C. A scheduled time for a resurvey of the home health agency to be conducted not later than the 18th month (or earlier, depending on the nature of the deficiencies) of the period of certification.

Certification of Noncompliance

The State agency will certify that a home health agency is not in compliance with the conditions of participation or, where a determination of eligibility has been made, that it is no longer in compliance where:

- A. The home health agency is not in compliance with one or more of the statutory requirements, or
- B. The home health agency has deficiencies of such character as to seriously limit its capacity to render adequate care or to place health and safety of individuals in jeopardy, and consultation to the home health agency has demonstrated that there is no early prospect of such significant improvement as to establish substantial compliance as of a later beginning date, or
- C. After a previous period or part thereof for which the home health agency was certified with a finding of significant deficiencies, there is a lack of progress toward a removal of deficiencies which the State agency finds are adverse to the health and safety of individuals being served.

If, on the basis of a State agency certification, it is determined by the Department of Health, Education, and Welfare that the home health agency no longer substantially meets the conditions of participation, the agreement under which the home health agency participates in the program may be terminated after reasonable notice and opportunity for a hearing.

Documentation of Findings

The findings of the State agency with respect to each of the conditions of participation should be adequately documented. Where the State agency certification to the Department of Health, Education, and Welfare is that a home health agency is not in compliance with the conditions of participation, such documentation should include a report of all consultation which has been undertaken in an effort to assist the home health agency to comply with the conditions, a report of the home health agency's responses with respect to the consultation, and the State agency's assessment of the prospects for such improvements as to enable the home health

agency to achieve substantial compliance with the conditions.

Authorization for Special Certification in Areas Where Necessary To Provide Access to Home Health Services

Where, by reason of isolated location, the denial of eligibility of a home health agency to participate would seriously limit the access of beneficiaries to the services of participating home health agencies, a home health agency may, upon recommendation by the State agency, be approved by the Department of Health, Education, and Welfare as a provider of services. Such approvals will be granted

only where there are no deficiencies of such character and seriousness as to place health and safety of individuals in jeopardy. A home health agency receiving this special approval will be expected to furnish information showing the extent to which it is making the best use of its resources to improve its quality of care. Resurveys of such agencies will be made at least annually.

Each case will have to be decided on its individual merits; and while the degree and extent of compliance will vary, the home health agency *must*, as a minimum, *meet* all of the statutory conditions in Section 1861(o)(1)-(4), in addition to meeting such other requirements as the Secretary finds necessary under Section 1861(o)(5).

THE HOME HEALTH AGENCY

This section presents conditions of participation related to the purpose and structure of the agency and organizational measures to assure patient care of high quality.

Condition of Participation

I. PRIMARY FUNCTIONS

The Primary Functions of the Home Health Agency¹ Include the Provision of Skilled Nursing Services and Other Therapeutic Services on a Visiting Basis in a Place of Residence Used as the Individual's Home.²

A. Provisions of services.

The agency's bylaws, or the equivalent thereof, state explicitly that the home health agency provides skilled nursing and other therapeutic services directly, or, in the case of a public or voluntary non-profit health agency, if it provides directly only skilled nursing services or only other therapeutic services, that it furnishes through arrangements with other public or voluntary non-profit agencies the services which it does not provide directly.³ A charter, an official statement of objectives, or the agency's governing policies are the equivalent of bylaws.

B. Subdivision operating as home health agency.

When a subdivision of an agency (e.g., the home care department of a hospital or the nursing division of a health department) applies for participation, the subdivision rather than the parent organization meets the conditions of participation as a home health agency and maintains records in such a way that subdivision activities and expenditures attributable to services provided under the health insurance program are identifiable. The parent organization may determine who signs the agreement and other official documents, and who receives and disburses funds.

¹ For purposes of post-hospital home health benefits under Part A of Title XVIII of the Social Security Act, the term home health agency does not include any agency or organization which is primarily for the care and treatment of mental diseases.

² See conditions of participation for skilled nursing services and other therapeutic services on pp. 11-14.

³ See conditions of participation for arrangements for services on pp. 15-16.

Condition of Participation

II. SKILLED NURSING AND ONE OTHER THERAPEUTIC SERVICE

In Addition to Skilled Nursing Services, the Agency Provides at Least One of the Following Other Therapeutic Services: i.e., Physical, Speech, or Occupational Therapy, Medical Social Services, or Home Health Aide Services.

Condition of Participation

III. AGENCY SUPERVISION

The Home Health Agency Designates a Physician or Registered Professional Nurse To Supervise the Agency's Performance in Providing Home Health Services in Accordance With the Orders of the Physician Responsible for the Care of the Patient and Under a Plan of Treatment Established by Such Physician.⁴

A. Where a nurse is designated.

It is preferable that an agency which designates a registered professional nurse appoint a public health nurse.

Condition of Participation

IV. ADVISORY GROUP OF PROFESSIONAL PERSONNEL

Policies Covering Skilled Nursing and Other Therapeutic Services, and the Professional Health Aspects of Other Policies, Are Established With the Approval of and Subject to Regular Review by a Group of Professional Personnel Which Includes a Licensed Physician and a Registered Professional Nurse.

A. Composition of group.

1. This group might be, for example: (a) an advisory committee to the agency's executive council or board of directors; (b) a subcommittee of such council or board; or (c) other similar arrangement.

⁴ See p. 17 for conditions of participation relating to "plan of treatment."

2. Some member or members of the professional group are persons not employed by the agency.
3. It is preferable that the registered professional nurse member be a public health nurse.
4. It is desirable for the group to include lay persons knowledgeable in health affairs and also to have a wide range of professional representatives such as medical social worker; nutritionist; speech, physical, and occupational therapists.

Condition of Participation

V. SERVICE TO HOMEBOUND PATIENTS ON PART-TIME OR INTERMITTENT BASIS

The Agency Is Organized, Staffed and Equipped To Provide Service to Homebound Patients on a Part-Time or Intermittent Basis.

A. Definition of homebound patient.

A homebound patient is one who is essentially confined to his place of residence for health reasons, although he may be ambulatory and may be able to leave his place of residence with or without the aid of another person.

B. Definition of part-time or intermittent.

Most patients will require service a few hours a day, several times a week. Some may require longer service on one day than on other days and such adjustments are to be encouraged. Occasionally, service for a full day may need to be provided for a short period of time when, because of unusual circumstances, neither the alternative of part-time care nor hospitalization is feasible.

Condition of Participation

VI. PERSONNEL POLICIES

The Agency Has Written Policies Concerning Qualifications, Responsibilities, and Conditions of Employment for Each Type of Personnel (Including Licensure Where This Is Required by State Law).

A. Content of personnel policies.

The policies are written and available to staff as well as to the group of professional personnel and cover:

1. Wage scales, hours of work, vacation and sick leave.

2. A plan for pre-employment and periodic medical examination, tuberculin test and/or chest X-ray, serology, and other appropriate tests.
3. A plan for orientation of all health personnel to the policies and objectives of the agency.
4. Periodic evaluation of employee performance.
5. Job descriptions for each category of health personnel which are specific and include the type of activity each may carry out.

Condition of Participation

VII. EVALUATION

The Agency Has Procedures Which Provide for Systematic Evaluation of Its Program at Least Once Every Two Years.

A. Method of program evaluation.

1. There are measures to determine whether the policies established with the approval of the group of professional personnel are followed in providing services. These should include a review of patient records on a sample basis in order to determine that services are being used appropriately and the extent to which the needs of the patients the agency serves are being met both quantitatively and qualitatively.
2. There is a mechanism for reviewing the overall management aspects of its service to assure economy and efficiency of operation.
3. Agency staff and/or its professional group may conduct the evaluation itself. Alternatively, the agency may seek the advice of persons or organizations outside the agency.

Condition of Participation

VIII. LICENSURE

The Home Health Agency, in a Community Where State or Applicable Local Law Provides for the Licensing of Agencies of This Nature, Is Licensed Pursuant to Such Law, or Approved by the State or Local Licensing Agency as Meeting the Standards for Licensure.

A. General.

The home health agency may be a public agency or a private non-profit or proprietary organization.

B. *Private non-profit organization.*

To qualify as a home health agency, a private non-profit organization presents proof of its exemption from Federal income tax pursuant to Section 501 of the Internal Revenue Code of 1954.

C. *Proprietary organization.*

To qualify as a home health agency, a proprietary organization which is not a private organi-

zation exempt from Federal income taxation under section 501 of the Internal Revenue Code of 1954 (or a subdivision of such organization) is licensed as a home health agency pursuant to State law, and meets all other conditions of participation. If no State law exists for the licensure of such an agency, it cannot be certified for participation in the health insurance program.



HOME HEALTH SERVICES

This section describes each type of home health services that may be paid for by the health insurance program and presents the necessary conditions concerning them.

Condition of Participation

IX. SKILLED NURSING SERVICE

Skilled Nursing Service Is Provided By or Under the Supervision of Registered Professional Nurse(s) Currently Licensed by the State.

A. Professional nursing services—duties.

Professional nursing services are services given in accordance with a physician's orders which require the competencies of a registered professional nurse, preferably a qualified public health nurse. Skilled nursing includes such duties as the following:

1. Evaluates and regularly re-evaluates the nursing needs of the patient;
2. Develops and implements the nursing care plan for the patient;
3. Provides nursing services, treatments, and diagnostic and preventive procedures requiring substantial specialized skill;
4. Initiates preventive and rehabilitative nursing procedures as appropriate for the patient's care and safety;
5. Observes signs and symptoms and reports to the physician reactions to treatments, including drugs, and changes in the patient's physical or emotional condition;
6. Teaches, supervises, and counsels the patient and family members regarding the nursing care needs and other related problems of the patient at home;
7. Supervises and trains other nursing service personnel.

B. Registered professional nurse—qualifications.

A registered professional nurse is currently licensed by the State as a registered professional nurse and preferably has one year of experience as a professional nurse.

C. Public health nurse—qualifications.

A public health nurse is licensed to practice professional nursing in the State and has completed a baccalaureate degree program approved by the National League for Nursing for public health nursing preparation or post-baccalaureate study

which includes content approved by the National League for Nursing for public health nursing preparation.

D. Practical nursing—duties.

Practical nursing services are given by a licensed practical nurse or licensed vocational nurse working under the supervision of a registered professional nurse. Practical nursing includes such duties as the following:

1. Observes, records, and reports to supervisor on the general physical and mental conditions of the patient;
2. Administers prescribed medications and simple treatments as permitted by State or local regulations;
3. Assists the physician and/or registered professional nurse in performing specialized procedures;
4. Prepares equipment for treatments, including sterilization and observation of aseptic techniques;
5. Assists the patient with activities of daily living and encourages appropriate selfcare.

E. Practical nurse—qualifications.

A practical nurse or vocational nurse is licensed by the State and preferably has at least one year of nursing experience under the supervision of a registered professional nurse.

Condition of Participation

X. PHYSICAL THERAPY

When an Agency Provides or Arranges for Physical Therapy, Service Is Given in Accordance With a Physician's Orders By or Under the Supervision of a Qualified Physical Therapist.

A. Physical therapy—duties.

Physical therapy includes such duties as the following:

1. Assists the physician in evaluating patients by applying diagnostic and prognostic muscle, nerve, joint, and functional ability tests;

2. Treats patients to relieve pain, develop or restore function, and maintain maximum performance, using physical means, such as exercise, massage, heat, water, light, and electricity, for example:

- a. Directs and aids patients in active and passive exercises, muscle re-education, and gait and functional training, activities of daily living including transfer activities and prosthetic training;
- b. Makes use of equipment such as ultraviolet and infrared lamps, low voltage generators, diathermy, and ultrasonic machines;
- c. Gives whirlpool and contrast baths, and applies moist packs;

3. Arranges for the provision on an outpatient basis of services in b. and c. above which cannot be given in the patient's home;
4. Observes, records, and reports to the physician the patient's reaction to treatment and any changes in the patient's condition;
5. Instructs patients in care and use of wheelchairs, braces, crutches, canes, and prosthetic and orthotic devices;
6. Instructs other health team personnel including, when appropriate, home health aides, and family members in certain phases of physical therapy with which they may work with the patient;
7. Instructs family on patient's total physical therapy program.

B. Physical therapist—qualifications.

A physical therapist is a graduate of a program in physical therapy approved by the Council on Medical Education of the American Medical Association in collaboration with the American Physical Therapy Association, or its equivalent, and when applicable, is licensed or registered by the State.

Condition of Participation

XI. SPEECH THERAPY

When an Agency Provides or Arranges for Speech Therapy, Service in Speech Pathology or Audiology Is Given in Accordance With a Physician's Orders and By or Under the Supervision of a Qualified Speech Therapist.

A. Speech therapy—duties.

Speech therapy includes such duties as the following:

1. Assists the physician in evaluation of the patient to determine the type of speech or language disorder and the appropriate corrective therapy;
2. Provides rehabilitative services for speech and language disorders;
3. Records and reports to the physician the patient's reaction to treatment and any changes in the patient's condition;
4. Instructs other health team personnel and family members in methods of assisting the patient to improve and correct speech disabilities.

B. Speech therapist—qualifications.

A speech therapist is certified by the American Speech and Hearing Association, or has completed the academic requirements and is in the process of accumulating the necessary supervised work experience required for certification.

Condition of Participation

XII. OCCUPATIONAL THERAPY

When an Agency Provides or Arranges for Occupational Therapy, Services Are Given in Accordance With a Physician's Orders and By or Under the Supervision of a Qualified Occupational Therapist.

A. Occupational therapy—duties.

Occupational therapy includes such duties as the following:

1. Assists the physician in evaluating the patient's level of function by applying diagnostic and prognostic procedures;
2. Guides the patient in his use of therapeutic creative and selfcare activities for the purpose of improving function;
3. Observes, records, and reports to the physician the patient's reaction to treatment and any changes in the patient's condition;
4. Instructs other health team personnel including, when appropriate, home health aides and family members in certain phases of occupational therapy in which they may work with the patient.

B. Occupational therapist—qualifications.

An occupational therapist is registered by the American Occupational Therapy Association or is a graduate of a program in occupational therapy approved by the Council on Medical Education of the American Medical Association in collaboration with the American Occupational Therapy Association and engaged in the required supervised clinical experience period prerequisite to registration by the American Occupational Therapy Association.

C. Occupational therapy assistant—qualifications.

An occupational therapy assistant has successfully completed a training course approved by the American Occupational Therapy Association and is certified by that body as a certified occupational therapy assistant.

Condition of Participation

XIII. AIDES TO PHYSICAL, SPEECH, AND OCCUPATIONAL THERAPISTS

When the Services of Aides or Other Personnel Providing Supplementary Services Are Utilized in Providing Home Health Services, They Are Trained and Supervised by Appropriate Professional Personnel.

Condition of Participation

XIV. MEDICAL SOCIAL SERVICES

When an Agency Provides or Arranges for Medical Social Services, They Are Given Under Direction of a Physician By or Under the Supervision of a Qualified Medical Social Worker.

A. Medical social services—duties.

Medical social services include such duties as the following:

1. Assists the physician and other members of the health team in understanding significant social and emotional factors related to patient's health problems;
2. Assesses the social and emotional factors in order to estimate the patient's capacity and potential to cope with problems of daily living;
3. Helps the patient and his family to understand, accept, and follow medical recommendations and provides services planned to

restore the patient to optimum social and health adjustment within his capacity;

4. Assists patients and their families with personal and environmental difficulties which predispose toward illness or interfere with obtaining maximum benefits from medical care;
5. Utilizes resources, such as family and community agencies, to assist patient to resume life in the community or to learn to live within his disability.

B. Medical social worker—qualifications.

A medical social worker is a graduate of a school of social work accredited by the Council on Social Work Education and has had social work experience in a hospital, outpatient clinic, medical rehabilitation or medical care program.

C. Social work assistant—qualifications.

A social work assistant has a baccalaureate degree and the agency provides on-the-job training in medical social service tasks and assignments.

Condition of Participation

XV. HOME HEALTH AIDE SERVICES

When an Agency Provides or Arranges for Home Health Aide Services, the Aides Are Assigned Because the Patient Needs Personal Care. The Services Are Given Under a Physician's Orders and Are Supervised by a Registered Professional Nurse. When Appropriate, Supervision May Be Given by a Physical, Speech, or Occupational Therapist.

A. Personal care for patient.

The title used for this class of personnel varies among agencies but the duties the aides perform are essentially personal care for the patient:

1. Helping patient with bath, care of mouth, skin, and hair;
2. Helping patient to bathroom or in using bed pan;
3. Helping patient in and out of bed, assisting with ambulation;
4. Helping patient with prescribed exercises which the patient and home health aide have been taught by appropriate professional personnel;
5. Assisting with medications, ordinarily self-

administered, that have been specifically ordered by a physician;

6. Performing such incidental household services as are essential to the patient's health care at home and necessary to prevent or postpone institutionalization.

Condition of Participation

XVI. SELECTION OF HOME HEALTH AIDES

The Selection of Each Potential Home Health Aide Takes Into Account Ability To Read and Write, To Understand and Carry Out Directions or Instructions, and To Record Messages and Keep Simple Records.

A. *Recruitment policies and procedures.*

Because home health aides may often be recruited from persons who have had little formal education and no health training, agencies need to establish and maintain specific policies concerning their selection. In addition to the capacities expressed in the condition, recruitment policies and procedures should take into account:

1. Emotional and mental maturity, and
2. Interest in and sympathetic attitude towards caring for the sick at home.

Condition of Participation

XVII. TRAINING OF HOME HEALTH AIDES

The Home Health Agency Determines That Home Health Aides Receive or Have Received a Basic Training Program for Home Health Aides.

A. *Faculty for basic training.*

Training in personal care services is given by a registered professional nurse (preferably a public health nurse). Physicians, nutritionists, physical therapists, medical social workers, and other health personnel are involved in appropriate aspects of the training program.

B. *Basic training content.*

The following topics suggest the appropriate content for the basic training:

1. The role of the home health aide as a member of the health services team.
2. Instruction and supervised practice in personal care services of the sick at home,

including personal hygiene and activities of daily living.

3. Principles of good nutrition and nutritional problems of the sick and elderly.
4. Preparation of meals including special diets.
5. Information on the process of aging and behavior of the aged.
6. Information on the emotional problems accompanying illness.
7. Principles and practices of maintaining a clean, healthy, and safe environment.
8. What to report to the supervisor.
9. Recordkeeping (when applicable).

C. *Training—orientation.*

Orientation of all home health aides to the agency's program should include:

1. Policies and objectives of the agency.
2. Information concerning the duties of a home health aide.
3. The functions of other health personnel employed by the agency and how they relate to each other in caring for the patient.
4. Information about other community agencies.
5. Ethics and confidentiality.

D. *Training on the job.*

In addition to basic training and orientation, the home health aide should receive on-the-job instruction in carrying out procedures, and continuing in-service training.

Condition of Participation

XVIII. SUPERVISION OF HOME HEALTH AIDES

The Decision To Assign a Home Health Aide to a Particular Case Is Made in Accordance With the Plan of Treatment.⁵ In Each Case a Registered Professional Nurse Decides Which Personal Care Services a Particular Home Health Aide Should Give. The Home Health Aide Is Not Permitted To Decide by Herself What Personal Care Services She Will Give.

A. *Assignment of home health aides.*

In deciding whether to provide home health aide service and which aide to assign, account will be taken of:

1. Successful completion of basic training.

⁵ See p. 17 for conditions of participation concerning plan of treatment.

2. Patient's needs.
3. The abilities of specific aides.
4. The amount of supervision available.
5. What the family can do for the patient.

B. Supervision of home health aides.

The professional nurse supervisor should provide direct supervision as necessary and can be readily available at other times by telephone. The supervisor should be constantly evaluating the home health aide in terms of the aide's ability to carry out assigned duties, to relate well to the homebound patient, and to work effectively as a member of a team of health workers. When the home health aide carries out, with the patient, simple procedures as an extension of physical, speech, or occupational therapy, supervision is also provided by the appropriate professional therapist.

Condition of Participation

XIX. SERVICES ARRANGED FOR WITH ANOTHER APPROVED PROVIDER

When a Home Health Agency Makes Arrangements for the Provision of Home Health Services Which It Does Not Provide Directly With Another Agency Which Is Approved As a Provider of Services, There Is a Written Statement Regarding the Services To Be Provided and the Financial Arrangements.

A. Illustrative examples of arrangements are:

1. The home care department of a hospital arranges for the provision of nursing services by a visiting nurse association, the nursing division of a health department or a combination agency.
2. Three hospitals join together to organize a single home health program to serve ex-patients of all the hospitals and other patients in the community who do not need hospital care but are ill and homebound. Each hospital is an approved provider of hospital care. One of the hospitals agrees to serve as the core agency and to seek certification as a home health agency. The core agency appoints a physician or registered professional nurse to supervise agency operations. The other two hospitals each appoint a coordinator, e.g., a physician, nurse or social worker.

Physical, speech, and occupational therapy are provided by a combination of the part-time services of such personnel in each hospital. Nursing services are arranged for with the visiting nurses' association.

3. In some communities, a public or non-profit voluntary health agency administers a community-wide program which involves several or many hospitals, the Visiting Nurse Association and/or the health department. The primary functions of this type of home health agency are (a) the continuing evaluation of patient needs, (b) assigning patients with fairly uncomplicated needs directly to the Visiting Nurse Association or the health department nursing service, and (c) arranging for and coordinating the services of the several hospitals and nursing organizations in providing a comprehensive array of services to patients with complicated needs. The agency usually employs a full-time nurse administrator, a part-time physician coordinator and medical social workers. The medical social workers provide direct services to patients. The physician coordinator maintains liaison with the physician responsible for the patient's care. In these communities there could be certified as home health agencies (a) some or all of the hospitals involved; (b) the central coordinating agency; (c) the Visiting Nurse Association; and (d) the health department nursing service.

Condition of Participation

XX. SERVICES ARRANGED FOR WITH A NON-PARTICIPATING PROVIDER

When a Home Health Agency Arranges for Services With an Agency That Is Not an Approved Provider of Services, a Contract Is Written.

A. Contract provisions.

The contract includes all of the following points:

1. Designates the services which are being arranged for.
2. Specifies the period of time the contract is to be in effect (if for a specified time) and how frequently it is to be reviewed. Preferably, the contract should be reviewed and renewed yearly.

3. Describes how the contracted personnel are to be supervised.
4. States that home health services provided to the patient are in accordance with a plan established by the patient's physician in conjunction with home health agency staff and, when appropriate, others involved in the patient's care. Services provided are to be within the scope and limitations set forth in the plan and may not be altered in type, scope, or duration by the secondary agency.
5. Assures that personnel and services contracted for meet the same requirements as those specified for home health agency personnel and services, including personnel qualifications, functions, supervision, orientation, and in-service training.
6. Specifies the method of determining charges

and reimbursement by the home health agency for specific services contracted for. The contracting agency does not bill the patient or the health insurance program.

B. *Kinds of arrangements.*

Kinds of Arrangements with a Nonparticipating Agency:

1. A participating home health agency arranges for home health aides from a family service association and/or an independent homemaker service which is not eligible as a home health agency.
2. A participating home health agency arranges for other therapeutic services to be provided in the patient's place of residence from a health agency which is not eligible as a provider of service.

ACCEPTANCE OF PATIENTS, PLAN OF TREATMENT, AND CLINICAL RECORDS

This section combines the statutory conditions of participation which appear in Section 1861(o) concerning clinical records with the closely related health and safety conditions which grow out of "plan of treatment established by a physician" in Section 1861(m) and the relevant requirement concerning the desirability and practicality of accepting patients for home health care.

Condition of Participation

XXI. ACCEPTANCE OF PATIENTS

The Home Health Agency Has Written Policies To Be Followed in Making Decisions of the Desirability and Practicality of Accepting Patients for Care. Such Decisions Are Based on Medical, Nursing and Social Information Provided by the Physician Responsible for the Patient's Care, Institutional Personnel, and Staff of the Home Health Agency.

A. Considerations relevant to the acceptance of patients include:

1. Adequacy and suitability of agency personnel and resources to provide the services required by the patient.
2. Attitudes of patient and his family toward his care at home.
3. Comparative benefit to the patient's health of care at home as distinguished from care in a hospital or extended care facility.
4. Reasonable expectation that patient's medical, nursing, and social needs can be met adequately in his residence, including a plan to meet medical emergencies.
5. Adequate physical facilities in the patient's residence for his proper care.
6. Availability of family or substitute family member able and willing to participate in patient's care.

B. The following illustrates this condition:

Although the provision of skilled nursing services is a basic condition of participation to qualify a home health agency as a provider of service, not all persons accepted for home health services will require skilled nursing. Some may require skilled nursing only on an intermittent basis while requiring physical or speech therapy fairly regularly. Also, as a patient's condition changes

and a home health aide has been taught to provide him with personal care services, the aide's service supervised by a nurse may for a time be the principal visiting service.

Condition of Participation

XXII. ESTABLISHMENT AND REVIEW OF PLAN OF TREATMENT

A Home Health Agency Has Established Policies and Procedures for Assuring That Services and Items To Be Provided Are Specified Under a Plan of Treatment Established and Regularly Reviewed by the Physician Who Is Responsible for the Care of the Patient.⁶

A. *Plan of treatment.*

The original plan of treatment is signed by the physician who is responsible for the care of the patient and incorporated in the record maintained by the agency for the patient. The total plan is reviewed by the attending physician, in consultation with agency professional personnel at such intervals as the severity of the patient's illness requires, but in any instance, at least once every two months. The professional registered nurse, physical, occupational, and speech therapists are expected to bring to the attention of the physician changes in the patient's condition which indicate the need for altering the treatment plan or for terminating services.

⁶ For the purpose of the home health agency receiving payment, the physician certifies, when establishing the plan of treatment, that the patient is essentially homebound and requires the services specified in the plan of treatment. The physician recertifies at least once every two months that these factors are still applicable. Under Part A only, he also indicates that the services have been or will be provided to treat conditions reasonably related to those for which the beneficiary received services while in a hospital or extended care facility.

Condition of Participation

XXIII. PHYSICIAN'S ORIGINAL ORDERS AND CHANGES IN ORDERS

Original Orders of a Physician and All Changes in Orders for the Administration of Dangerous Drugs and Narcotics Are Signed by the Physician and Incorporated in the Patient Record Maintained by the Agency. All Other Changes in Orders Are Either Signed by the Physician or by a Registered Professional Nurse in the Agency if Such Changes Are Received Verbally by Her.

Condition of Participation

XXIV. CLINICAL RECORDS

The Home Health Agency Maintains for Each Patient a Clinical Record Which Covers the Services the Agency Provides Directly and Those Provided Through Arrangements With Another Agency; and Which Contains Pertinent Past and Current Medical, Nursing, Social, and Other Therapeutic Information, Including the Plan of Treatment.

A. *The patient record.*

The kinds of information which the patient record should contain are:

1. Admission data including:

- a. Identifying data: name, address, date of birth, sex, agency case number if it uses one, and social security number, and next of kin.
- b. Whether the home health services benefit is (a) post hospital, (b) post extended care facility or (c) neither; and names of institutions and dates of discharge for (a) and (b).

c. Date of admission for service.

d. Referring physician.

B. *Clinical notes.*

1. Clinical data including:

- a. Diagnoses: all conditions which the patient has and which are relevant to the plan of treatment.
- b. Nursing services: Level needed and frequency of visits (in agreement with the agency nursing staff); special care (dressing changes, catheter changes, etc.); observations, including specific observations to be brought to the immediate attention of the physician.
- c. Drugs: Type, dose, and frequency of each drug; caution concerning special side effects, drug allergies; nonprescription remedies which are contraindicated, e.g., aspirin with dicoumarol therapy.
- d. Diet: Regular or restricted.
- e. Activity: Degree allowed, e.g., bedrest with bathroom privileges.
- f. Rehabilitation plan: Activities of daily living, etc.
- g. Occupational, speech, and physical therapy: Specific instructions for each service needed.
- h. Medical social services.
- i. Home health aide services.
- j. Medical supplies; Special dressings needed, oxygen, etc.
Medical appliances: Special devices needed, e.g., crutches, oxygen tent, etc.

C. *Discharge notes:*

When home health services are terminated, the record should show the date and reason for termination (patient not in need of services, patient expired, transferred to home for aged, etc.).

SUPPLEMENTARY INFORMATION RELATED TO PROVISION OF HOME HEALTH SERVICES

This section deals *in general* with (1) other services and supplies, explains which are reimbursable and describes requirements concerning each; (2) "visits" and how to count them; (3) "spell of illness," "deductibles," and "co-insurance," and (4) financial recordkeeping. *Specific details* on these subjects will be issued in other documents.

This general information is included here in order that the agency which applies for certification and community groups which are establishing new home health agencies can anticipate the nature of their financial relationships with the health insurance system, with beneficiaries and with other agencies with which they "arrange for service."

OTHER SERVICES INCLUDED

Services of Interns and Residents. Services provided by an intern or resident-in-training under an approved teaching program may be included in home health services provided the home health agency is affiliated or under common control with the hospital and the teaching program is approved by:

- A. The Council on Medical Education of the American Medical Association or;
- B. In the case of an osteopathic hospital, by the Committee on Hospitals of the Bureau of Professional Education of the American Osteopathic Association;
- C. Or in the case of services by an intern or resident-in-training in the field of dentistry, by the Council on Dental Education of the American Dental Association.

Outpatient Services. Outpatient services provided as home health services are limited to physical, speech, or occupational therapy when the furnishing of such services involves the use of equipment which cannot be made available to the patient in his place of residence. The home health agency may arrange for such services from an approved hospital, extended care facility, outpatient department affiliated with a medical school, or from a rehabilitation center.

A "rehabilitation center" which is neither an approved hospital nor extended care facility is a facility providing medical services which are directed toward the restoration and adjustment of disabled individuals through treatment and training by competent personnel specially qualified in the various phases of the total rehabilitation process. The physical plant and equipment of such a rehabili-

tation center meets all applicable State and local legal requirements for construction, safety, health and design, including safety, sanitation and fire regulations, building codes and ordinances.

Medical Supplies and Appliances. Medical supplies include such items as: gauze, cotton, band aids, surgical dressings, catheters, surgical gloves, rubbing alcohol, irrigating solutions, intravenous fluids, and oxygen.

Medical appliances are items owned or rented by the home health agency and required by the patient to facilitate his treatment and rehabilitation. Medical appliances include such items as bedpans, wheelchairs, crutches, hospital beds, trapeze bars, oxygen tents, intermittent positive pressure machines, and air pressure mattresses.

SERVICES EXCLUDED

In addition to the general exclusions which are published elsewhere, the following items are specifically excluded from payment as home health services:

1. Meals-on-wheels.
2. Services of a domestic or housekeeping services unrelated to patient care.
3. Ambulance and special transportation of patients.
4. Drugs and biologicals other than medical supplies.
5. Expenses which constitute charges imposed by immediate relatives or members of household.
6. Dental services (other than service with respect to surgery related to the jaw or any structure contiguous to the jaw, or the reduction of any fracture of the jaw or any facial bone) in connection with the care, treatment, filling, removal, or replacement of teeth or structures directly supporting the teeth.

VISITS

For purposes of this program, the 100 visits to which all patients are entitled under Part A and the 100 visits to which patients who subscribe for Part B are also entitled mean: A visit to the patient in his home, or a visit by the patient to a medical facility, or a combination of the two. Two kinds of visits are to be counted:

1. A visit to a patient in his place of residence by a qualified health worker to provide nursing care, physical therapy, occupational therapy, speech therapy, medical social service, home health aide service or, in specified circumstances, the services of an intern or resident.
2. A visit by a patient on an outpatient basis to a hospital, medical clinic, extended care facility, or rehabilitation center when arrangements have been made by the home health agency for a service which involves the use of equipment which cannot be made available to the patient in his place of residence.⁷

Visits by agency personnel other than those specified in (1) above are not to be counted. In some programs, personnel employed by the agency to assist in the overall operation of the program, such as professional mental health, and nutrition personnel, visit patients in their homes. The salaries of this type of personnel may be taken into consideration in computing the basis for reimbursement.

Only one visit is recorded when a visit is made simultaneously by two or more persons of the same or different health disciplines to provide a single service, for which one person supervises or instructs the other.

Two visits are recorded when two persons of the same or different health disciplines visit the beneficiary at the same or different times during a twenty-four hour period for the purpose of providing separate and distinct types of services. Two visits are counted if a nurse and a physical therapist visit the beneficiary in his home at the same time or separately during the day so that the nurse may give a nursing service and the physical therapist may give resistive exercises. Similarly, two visits are recorded if a patient is taken to a hospital to receive outpatient therapy that could not be furnished in his own home—hydrotherapy, for example—and while there also receives speech therapy.

Each visit is counted in the rare situation when one health worker must visit the patient's home more than once during a day to provide services. If a nurse visits the patient twice during a day to administer an intramuscular injection, two visits are counted.

SPELL OF ILLNESS, DEDUCTIBLES, CO-INSURANCE

Under Part A up to 100 visits may be paid for if made (a) within one year after the beneficiary's most recent discharge from a hospital or extended care facility and (b) after the beginning of one spell of illness and before the beginning of the next. A "spell of illness" begins with the first day (not included in a previous spell of illness) on which the beneficiary is furnished inpatient hospital services or extended care services and which occurs in a month for which he is entitled to benefits under the basic health insurance program. A spell of illness ends when the patient has been out of a hospital or an extended care facility for 60 consecutive days.

Examples of number of visits allowed under the hospital insurance plan:

- a. If a patient is hospitalized on July 14, 1966, and discharged on August 9, 1966, 100 visits could be paid for between August 9, 1966, and August 8, 1967.
- b. If a patient is hospitalized on August 10, 1966, and is discharged on August 15, 1966, he is entitled to 100 visits from August 15, 1966, through August 14, 1967. If patient re-enters the hospital on September 30, 1966, after using 10 visits, is released on October 3, 1966, and the home health services plan is re-established, he is entitled to use the remaining 90 visits through October 2, 1967.
- c. If a patient is hospitalized on July 14, 1966, and discharged on August 9, 1966, 100 visits could be paid for between August 9, 1966, and August 8, 1967. However, if he enters the hospital again on October 10, 1966 (having been out of a hospital or extended care facility for 60 consecutive days), he begins a second spell of illness and, upon his discharge, would be eligible for another 100 visits irrespective of the number of visits used in connection with the first spell of illness. (The unused number of visits after the first spell of illness would be cancelled.) Therefore, it is pos-

⁷ See "Outpatient Services" on page 19.

sible for a beneficiary to have more than 100 visits paid for under the basic plan in a twelve-month period if more than one spell of illness occurs during that period.

Under Part A "deductible" and "co-insurance" provisions do not apply to home health services.

Under Part B up to 100 visits during a calendar year may be paid for on behalf of a beneficiary who has voluntarily enrolled in Part B. However, during the year 1966, a beneficiary may receive, under this Part, 100 visits in the period beginning July 1, 1966, and ending December 31, 1966.

Visits under this Part need not be preceded by inpatient care. They may supplement visits under Part A after the patient has received 100 visits following care in a hospital or extended care facility; or they may be provided to a patient who does not require care in a hospital or extended care facility.

The spell of illness concept does not apply to Part B.

"Deductible" and "co-insurance" both apply to Part B. In general, the annual deductible of \$50.00 must be made up of expenses for *covered* services. The deductible cannot be made up of expenditures for excluded services such as routine physical check-ups, prescription drugs, eyeglasses, etc.

RECORDS (STATISTICAL AND FINANCIAL)

The law provides that participating home health agencies shall be reimbursed in full for the reasonable cost of covered services minus "deductible" and "co-insurance" amounts for services under Part B. Reasonable costs will include both direct and indirect costs including normal standby costs of the agency.

In deciding what system of financial recording it wishes to adopt, the agency will need to know certain facts that underlie policies and procedures concerning payment which will be developed more fully for issuance in another document or manual. The following general principles applicable to financial recordkeeping are designed to describe methods which will be mutually satisfactory to the agency and to the Social Security Administration.

1. Every home health agency is free to choose its method of accounting within the broad limits indicated below.
2. The home health agency (and the agencies with which it may have arrangements for the provision of certain home health services), must maintain adequate financial and statistical records by which the cost of providing services can be determined. The financial records should support the determination of reasonable costs and be available for audit.
3. There must be consistency in the accounting methods used from year to year. If special circumstances make necessary a significant change in the accounting method from that used in preceding years, there should be mutual agreement between the provider and the intermediary as to the use of the new method and the effect of the change.
4. Payments to providers will be made at specified intervals but not less frequently than monthly. These will be tentative payments, based on estimates of current costs. At the end of each year, a statement of costs actually incurred shall be prepared. A retroactive adjustment will be made between the actual costs applicable to health insurance beneficiaries and the amount already paid to the home health agency during the year by the government (through tentative current payments) and by beneficiaries (through deductibles and co-insurance).
5. The rate of payment of the tentative payments during the year shall be based on the average rate per visit, or some similar basis, agreed upon with the intermediary. The agreed-upon rate should approximate current costs as closely as feasible in order to avoid a large retroactive adjustment at the end of the year.
6. When a home health agency arranges to purchase specified services from another agency, the latter agency must bill the home health agency for its services. The home health agency will, in turn, include the amounts billed by the second agency in its costs and it will be reimbursed for its reasonable costs including these costs.

APPENDIX A

The following excerpts from Public Law 89-97 define the terms "home health services," "post-hospital home health services," "home health agency," and "arrangements for certain services."

Section 1861(m). The term 'home health services' means the following items and services furnished to an individual, who is under the care of a physician, by a home health agency or by others under arrangements with them made by such agency, under a plan (for furnishing such items and services to such individual) established and periodically reviewed by a physician, which items and services are, except as provided in paragraph (7), provided on a visiting basis in a place of residence used as such individual's home—

(1) part-time or intermittent nursing care provided by or under the supervision of a registered professional nurse;

(2) physical, occupational, or speech therapy;

(3) medical social services under the direction of a physician;

(4) to the extent permitted in regulations, part-time or intermittent services of a home health aide;

(5) medical supplies (other than drugs and biologicals), and the use of medical appliances, while under such a plan;

(6) in the case of a home health agency which is affiliated or under common control with a hospital, medical services provided by an intern or resident-in-training of such hospital, under a teaching program of such hospital approved as provided in the last sentence of subsection (b); and

(7) any of the foregoing items and services which are provided on an outpatient basis, under arrangements made by the home health agency, at a hospital or extended care facility, or at a rehabilitation center which meets such standards as may be prescribed in regulations, and—

(A) the furnishing of which involves the use of equipment of such a nature that the items and services cannot readily be made available to the individual in such place of residence, or

(B) which are furnished at such facility while he is there to receive any such item or service described in clause (A), but not including transportation of the individual in connection with any such item or service;

excluding, however, any item or service if it would not be included under subsection (b) if furnished to an inpatient of a hospital.

Section 1861(n). The term 'post-hospital home health services' means home health services furnished an individual within one year after his most recent discharge from a hospital of which he was an inpatient for not less than 3 consecutive days or (if later) within one year after his most recent discharge from an extended care facility of which he was an inpatient entitled to payment under Part A for post-hospital extended care services, but only if the plan covering the home health services (as described in subsection (m)) is established within 14 days after his discharge from such hospital or extended care facility.

Section 1861(o). The term 'home health agency' means a public agency or private organization, or a subdivision of such an agency or organization, which—

(1) is primarily engaged in providing skilled nursing services and other therapeutic services;

(2) has policies, established by a group of professional personnel (associated with the agency or organization), including one or more physicians and one or more registered professional nurses, to govern the services (referred to in paragraph (1)) which it provides, and provides for supervision of such services by a physician or registered professional nurse;

(3) maintains clinical records on all patients;

(4) in the case of an agency or organization in any State in which State or applicable local law provides for the licensing of agencies or organizations of this nature, (A) is licensed pursuant to such law, or (B) is approved, by the agency of such State or locality responsible for licensing agencies or organizations of this nature, as meeting the standards established for such licensing; and

(5) meets such other conditions of participation as the Secretary may find necessary in the interest of the health and safety of individuals who are furnished services by such agency or organization; except that such term shall not include a private

organization which is not a nonprofit organization exempt from Federal income taxation under section 501 of the Internal Revenue Code of 1954 (or a subdivision of such organization) unless it is licensed pursuant to State law and it meets such additional standards and requirements as may be prescribed in regulations; and except that for purposes of Part A such term shall not include any agency or organization which is primarily for the care and treatment of mental diseases.

Section 1861(w). "The term 'arrangements' is limited to arrangements under which receipt of payment by the hospital, extended care facility, or home health agency (whether in its own right or as agent), with respect to services for which an individual is entitled to have payment made under this title, discharges the liability of such individual or any other person to pay for the services."

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APPENDIX B

**Home Health Agency Request to Establish Eligibility in the Health Insurance
for the Aged Program**

Instructions for Completing the Form



**HOME HEALTH AGENCY REQUEST TO ESTABLISH ELIGIBILITY
IN THE HEALTH INSURANCE FOR THE AGED PROGRAM**

All home health agencies desiring to establish their eligibility in the health insurance program should complete this form and return it to the State agency that is handling the certification process. If a return envelope is not provided, the name and address of the State agency may be obtained from the nearest Social Security Administration district office.

SUBMISSION OF THIS FORM AND ESTABLISHING ELIGIBILITY DOES NOT OBLIGATE A HOME HEALTH AGENCY TO PARTICIPATE. AN AGREEMENT WILL BE MADE AVAILABLE BY THE SOCIAL SECURITY ADMINISTRATION AT A LATER DATE TO HOME HEALTH AGENCIES WHO HAVE ESTABLISHED ELIGIBILITY. THERE IS NO COMMITMENT UNTIL THE AGREEMENT IS SIGNED.

DO NOT WRITE IN THIS SPACE

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DATE CERTIFIED
CERTIFICATION

I. Identifying Information	A. NAME OF AGENCY		STREET ADDRESS	
	CITY, COUNTY, AND STATE		ZIP CODE	TELEPHONE NO. (Including area code)
	NAME OF CHIEF ADMINISTRATIVE OFFICER		TITLE	
	B. NAME AND ADDRESS OF PARENT INSTITUTION (If applicable)			

ITEMS II THROUGH VI ARE FOR STATISTICAL PURPOSES

II. Type of Home Health Agency (Check one)	1 <input type="checkbox"/> Visiting Nurse Association	4 <input type="checkbox"/> Rehabilitation Facility Based Program	7 <input type="checkbox"/> Other (Specify)	
	2 <input type="checkbox"/> Combination Government and Voluntary Agency	5 <input type="checkbox"/> Hospital Based Program		
	3 <input type="checkbox"/> Official Health Agency	6 <input type="checkbox"/> Extended Care Facility Based Program		
III. Type of Control (Check one)	01 <input type="checkbox"/> Voluntary Non-Profit Other Than Church	05 <input type="checkbox"/> Other State Departments	09 <input type="checkbox"/> Combination Govt. and Voluntary	
	02 <input type="checkbox"/> Voluntary Non-Profit Church	06 <input type="checkbox"/> City or County Health Department	10 <input type="checkbox"/> Proprietary	
	03 <input type="checkbox"/> State Health Department	07 <input type="checkbox"/> City or County Welfare Department	11 <input type="checkbox"/> Other (Specify)	
	04 <input type="checkbox"/> State Welfare Department	08 <input type="checkbox"/> Other City or County Departments		
IV. Services Provided by Agency Staff or Under Arrangements (Check all applicable)	01 <input type="checkbox"/> Nursing Care	06 <input type="checkbox"/> Home Health Aide— Homemaker Service	11 <input type="checkbox"/> Vocational Guidance	
	02 <input type="checkbox"/> Physical Therapy	07 <input type="checkbox"/> Interns and Residents	12 <input type="checkbox"/> Other (Specify)	
	03 <input type="checkbox"/> Occupational Therapy	08 <input type="checkbox"/> Nutritional Guidance		
	04 <input type="checkbox"/> Speech Therapy	09 <input type="checkbox"/> Pharmaceutical Service		
	05 <input type="checkbox"/> Medical Social Services	10 <input type="checkbox"/> Appliances and Equipment Service		
Some of these services are not reimbursable under the Health Insurance Program. See the Conditions of Participation for those services which are reimbursable.				
V. Physicians	NUMBER OF PHYSICIANS ON THE MEDICAL STAFF			
VI. Number of Employees on the Agcy. Staff (Full-Time Equivalents)	A. REGISTERED PROFS- SIONAL NURSES	B. LICENSED PRACTICAL NURSES	C. QUALIFIED PHYSICAL THERAPISTS	D. QUALIFIED OCCUPATIONAL THERAPISTS
	E. QUALIFIED SPEECH THERAPISTS	F. HOME HEALTH AIDES	G. QUALIFIED MEDICAL SOCIAL WORKERS	H. ALL OTHERS
	SIGNATURE OF AUTHORIZED OFFICIAL		TITLE	
			DATE	

INSTRUCTIONS FOR COMPLETING HOME HEALTH AGENCY REQUEST TO ESTABLISH ELIGIBILITY IN THE HEALTH INSURANCE FOR THE AGED PROGRAM (SSA-1515)

The filing of this request for eligibility will initiate the process of obtaining a decision as to whether the Conditions of Participation are met. A home health agency that establishes its eligibility may later enter into an agreement to become a participating home health agency.

Submission of this form and establishing eligibility does not obligate a home health agency to participate. An agreement will be made available by the Social Security Administration at a later date to home health agencies who have established eligibility. There is no commitment until the agreement is signed.

Please do not delay returning the form even though certain information is not now available. Assistance in filling out the form is available from the State agency.

General Instructions

Please answer all questions as of the current date.

Return the original and first copy to the State agency in the envelope provided; retain the second copy for your files. If a return envelope is not provided, the name and address of the State agency may be obtained from the nearest Social Security Administration district office.

Detailed Instructions for Specific Questions

These instructions are designed to clarify certain questions on the form. Instructions are listed in question order, for easy reference. No instructions have been given for questions considered self-explanatory.

Question I—Identifying Information

- A. Insert the full name under which the home health agency operates.
- B. If a subdivision of a larger institution, provide the name and address of the parent institution.

Question II—Type of Home Health Agency

Check the one category that is most descriptive of the type of home health agency.

2. *Combination Government and Voluntary Agency*—an agency which is jointly administered by an official health agency and a voluntary non-profit agency (e.g., a home health agency jointly administered by a State or local health department and a visiting nurse association).

Question III—Type of Control

Check the one category that is most descriptive of

the type of organization operating the home health agency.

Question IV—Services Provided by Agency Staff or Under Arrangements

Check all the services that are normally provided by the agency staff or under formal arrangements with another agency or health facility.

Check *Interns and Residents* only if the home health agency is affiliated or under common control with a hospital and the medical services are provided by an intern or resident-in-training of such hospital under an approved teaching program.

Check *Nutritional Guidance* only if the home health agency has a qualified dietician (e.g., one meeting the American Dietetic Association's standards for qualification) on the staff, or the services of a qualified dietician are provided on a consulting basis.

Check *Pharmaceutical Service* only if pharmaceuticals are provided on a regular basis to patients of the home health agency by a pharmacy affiliated with the agency or under a written or verbal agreement to provide such service.

Check *Appliances and Equipment and/or Vocational Guidance*, only if such services are routinely available for patients of the agency on a continuing basis. Do not check if such services are solely a referral to another agency or organization that furnishes such services.

Question VI—Number of Employees on the Agency Staff

Include only those personnel regularly employed. Include members of religious orders. Exclude all trainees, private-duty nurses, and volunteers. To arrive at full-time equivalents, add the total number of hours worked by all employees in each classification in the week ending prior to the week of filing the request and divide by the number of hours in the standard work week. If the result for each classification is not a whole number, express it as a fraction (e.g., $2\frac{1}{4}$).

Include in the count of *qualified physical therapists* only those physical therapists who are graduates of a program in physical therapy approved by the Council on Education of the American Medical Association in collaboration with the American Physical Therapy Association, or its equivalent, and, when applicable, are licensed or registered by the State.

Include in the count of *qualified occupational therapists* only those occupational therapists who are registered by the American Occupational Therapy Association or are graduates of a program in occupational therapy approved by the Council on Medical Education of the American Medical Association, and are engaged in the required supervised clinical experience period prerequisite to registration by the American Occupational Therapy Association.

Include in the count of *qualified speech therapists* only those speech therapists who are certified by the

American Speech and Hearing Association or have completed the academic requirements and are in the process of accumulating the necessary supervised work experience required for certification.

Include in the count of *qualified medical social workers* only those medical social workers who are graduates of a school of social work accredited by the Council on Social Work Education and have had social work experience in a hospital, outpatient clinic, medical rehabilitation or medical care program.









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CONDITIONS OF PARTICIPATION FOR EXTENDED CARE FACILITIES



U.S. DEPARTMENT OF
HEALTH, EDUCATION, AND WELFARE
Social Security Administration

HIM-3 (3-66)



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CONDITIONS OF PARTICIPATION FOR EXTENDED CARE FACILITIES

Introduction

In order to participate as an extended care facility in the health insurance program for the aged, an institution must be an "extended care facility" within the meaning of section 1861(j) of the Social Security Act.¹ This section of the law states a number of specific requirements which must be met by participating extended care facilities and authorizes the Secretary of Health, Education, and Welfare to prescribe other requirements considered necessary in the interest of health and safety of beneficiaries. The requirements included in the statute and the additional health and safety requirements to be prescribed by the Secretary are incorporated into the conditions of participation for extended care facilities.

The conditions of participation for extended care facilities and related policies, as set forth herein, will be reflected in regulations of the Department of Health, Education, and Welfare. Meanwhile, the Social Security Administration is making the conditions available to extended care facilities as well as to State agencies and other organizations involved in the process of establishing the qualifications of institutions in order that interested institutions may apply for a determination of their eligibility to participate in the health insurance program. The law makes provision for the designation of State health agencies, or other State agencies, to assist the Department in determining whether the conditions of participation have been met. The designated State agencies will certify to the Department of Health, Education, and Welfare institutions which meet the conditions and will provide consultation to institutions to assist them to qualify. An institution which meets all of the specific statutory requirements and is found to be in substantial compliance with the conditions prescribed in regulations may, if it so desires, agree to become a participating extended care facility.

The conditions of participation have been developed in accordance with the requirements, authorizations, and limitations of the law.² Concurrently with the

release of these materials to interested individuals, organizations and agencies, the Department of Health, Education, and Welfare will proceed with the necessary action to establish conforming regulations. The official Notice of Proposed Rule Making and notice of the opportunity for submission of data, comments, and arguments relating to the proposed regulations are being provided in accordance with the regular procedure of publication in the Federal Register.

Conditions of Participation

In the preparation of the conditions of participation, there has been extensive discussion and consultation with organizations and experts in the fields of hospital, nursing home, and medical care. Groups consulted included representatives of State health and welfare departments, the American Hospital Association, American Medical Association, American Nursing Home Association, American Association of Homes for the Aging, Joint Commission on Accreditation of Hospitals, American Nurses Association, American Osteopathic Association, among others. The conditions of participation have also been reviewed and endorsed by the Health Insurance Benefits Advisory Council, the statutory body established for the purpose of advising the Secretary on matters of general policy in the administration of this program and in the formulation of applicable regulations.

For an institution to be eligible for participation in the program, it must meet the specific statutory requirements of section 1861(j) as well as the additional conditions established in the interest of health and safety which are essential to the maintenance of quality of care and the adequacy of the services and facilities which the institution provides. It will not be unusual for extended care facilities to differ in the manner in which these conditions will be met. Variations in the type and size of the institutions and the nature and scope of services offered will be reflected in differences in the details of organization, staffing, and facilities. *However, the test will be whether there*

¹ The law excludes from participation any institution which is primarily for the care and treatment of mental diseases or tuberculosis.

² The law provides that the Secretary may, at the request of a State, approve higher health and safety requirements for

that State than are reflected in the conditions of participation for extended care facilities; and where a State or political subdivision imposes higher requirements on institutions as a condition for the purchase of services under a State plan approved under title I, XVI, or XIX of the Social Security Act, the Secretary is required to impose like requirements as a condition to the payment for services in such institutions in that State or subdivision.

is substantial compliance with the prescribed conditions of participation.

As a basis for a determination as to whether or not there is substantial compliance with the prescribed conditions in the case of any particular extended care facility, a series of standards, almost all interpreted by explanatory factors, are listed under each condition. These standards represent a broad range and variety of activities which such facilities may undertake or be pursuing in order to carry out the functions embodied in the conditions. Reference to these standards will enable the State agency surveying a facility to document the activities of the institution, to establish the nature and extent of its deficiencies, if any, with respect to any particular condition, and to assess the facility's need for improvement in relation to the prescribed conditions. In substance, the application of the standards, together with the explanatory factors, will indicate the extent and degree to which an extended care facility is complying with each condition.

Procedures for Establishing Eligibility to Participate

The Health Insurance for the Aged Act provides that the State agencies, operating under agreements with the Department, will be used by the Department in determining whether institutions meet the conditions of participation. Pursuant to these agreements, State agencies will certify to the Department findings as to whether extended care facilities are in substantial compliance with the conditions. Such certifications will include findings as to whether each of the conditions is substantially met. The Department, on the basis of such certification from the State agency, will determine whether or not an institution is an extended care facility eligible to participate in the health insurance program as a provider of services.

The decisions of the State agency represent recommendations to the Secretary. Notice of determination of eligibility or noneligibility made by the Department on the basis of a State agency decision will be sent to the institution concerned by the Social Security Administration after such review and professional consultation with the Public Health Service as may be required. If it is determined that the institution does not comply with the conditions of participation, the institution has a right to appeal the determination and request a hearing. If the final decision which an institution receives after an appeal is unfavorable, the institution may request judicial review by the Federal courts.

The appendix of this pamphlet contains samples of the forms and instructions which will be made available by State agencies to extended care facilities and which will be used to initiate the process of establishing

eligibility. In addition to utilizing information available in licensure or other files, State agencies will conduct such surveys as may be necessary to determine the degree to which the conditions are met. An extended care facility may obtain further information or assistance from the designated State agency or from the Regional Representative, Bureau of Health Insurance, Social Security Administration. The address of the designated State agency or the regional office can be secured from any district office of the Social Security Administration.

Principles for the Evaluation of Extended Care Facilities to Determine Whether They Are in Substantial Compliance With the Conditions of Participation

Extended care facilities will be considered in substantial compliance with the conditions of participation upon acceptance by the Secretary of findings, adequately documented and certified to by the State agency, showing that:

- A. The facility meets the specific statutory requirements^a of Section 1861(j) and is found to be operating in accordance with all conditions of participation with no significant deficiencies, or
- B. The facility meets the specific statutory requirements of section 1861(j) but is found to have deficiencies with respect to one or more conditions of participation which:
 1. It is making reasonable plans and efforts to correct, and
 2. Notwithstanding the deficiencies, it is rendering adequate care and is without hazard to the health and safety of individuals being served, taking into account special procedures or precautionary measures which have been or are being instituted.

Time Limitations on Certifications of Substantial Compliance

All initial certifications by the State agency to the effect that an extended care facility is in substantial compliance with the conditions of participation will be for a period of 1 year, beginning with January 1, 1967, or if later, with the date on which the facility is first found to be in substantial compliance with the conditions. State agencies may visit or resurvey institutions where necessary to ascertain continued compliance or to accommodate to periodic or cyclical survey programs. A State finding and certification to the Secretary that an institution is no longer in compliance (see next topic) may occur within a 1-year or subsequent

^a Statutory requirements incorporated in the conditions and standards are indicated by italics.

period of certification and will terminate the State certification as to compliance.

If an extended care facility is certified by the State agency as in substantial compliance under the provisions of paragraph B above, the following information will be incorporated into the finding and into the notice of eligibility to the facility:

- A. A statement of the deficiencies which were found, and
- B. A description of progress which has been made and further action which is being taken to remove the deficiencies, and
- C. A scheduled time for a resurvey of the institution to be conducted not later than the ninth month (or earlier, depending on the nature of the deficiencies) of the period of certification.

Certifications of Noncompliance

The State agency will certify that an institution is not in compliance with the conditions of participation or, where a determination of eligibility has been made, that an institution is no longer in compliance where:

- A. The institution is not in compliance with one or more of the statutory requirements of section 1861(j), or
- B. The institution has deficiencies of such character as to seriously limit the capacity of the institution to render adequate care or to place health and safety of individuals in jeopardy, and consultation to the institution has demonstrated that there is no early prospect of such significant improvement as to establish substantial compliance as of a later beginning date, or
- C. After a previous period or part thereof for which the institution was certified with a finding of significant deficiencies, there is a lack of progress toward a removal of deficiencies which the State agency finds are adverse to the health and safety of individuals being served.

If, on the basis of a State agency certification, it is determined by the Department of Health, Education, and Welfare that the institution does not substantially meet, or no longer substantially meets, the conditions of participation, an agreement for participation may not be accepted for filing or, if filed, may be terminated after reasonable notice and opportunity for a hearing.

Criteria for Determining Substantial Compliance

Findings made by a State agency as to whether an extended care facility is in substantial compliance with the conditions of participation require a thorough evaluation of the degree to which operation of a facility demonstrates adequate performance of the functions which are embodied in the conditions. The State evaluation will take into consideration:

- A. The degree to which each standard, as well as the total set of standards relating to a condition of participation, is met;
- B. When there is a deficiency in meeting a standard, whether the deficiency is one concerning the statutory requirements, all of which must be met by all extended care facilities (Sec. 1861(j), Public Law 89-97, see appendix);
- C. Whether the deficiency creates a hazard to health and safety;
- D. Whether the facility is making reasonable plans and efforts to correct the deficiency within a reasonable period.

Documentation of Findings

The findings of the State agency with respect to each of the conditions of participation should be adequately documented. Where the State agency certification to the Department of Health, Education, and Welfare is that an institution is not in compliance with the conditions of participation, such documentation should include a report of all consultation which has been undertaken in an effort to assist the institution to comply with the conditions, a report of the institution's responses with respect to the consultation, and the State agency's assessment of the prospects for such improvements as to enable the institution to achieve substantial compliance with the conditions.

Authorization for Special Certification in Areas Where Necessary to Provide Access to Extended Care Services

Where, by reason of isolated location, or the absence of sufficient facilities in an area, the denial of eligibility of an institution to participate would seriously limit the access of beneficiaries to participating extended care facilities, an institution may, upon recommendation by the State agency, be approved by the Department of Health, Education, and Welfare as a provider of services. Such approvals will be granted only where there are no deficiencies of such character and seriousness as to place health and safety of individuals in jeopardy. An institution receiving this special approval shall furnish information showing the extent to which it is making the best use of its resources to improve its quality of care. Resurveys of such institutions will be made at least semiannually.

Each case will have to be decided on its individual merits; and while the degree and extent of compliance will vary, the institution must, as a minimum, meet all of the statutory conditions in section 1861(j) (1)-(9), in addition to meeting such other requirements as the Secretary finds necessary under section 1861(j) (10).



Condition of Participation

I. COMPLIANCE WITH STATE AND LOCAL LAWS

THE EXTENDED CARE FACILITY IS IN CONFORMITY WITH ALL APPLICABLE FEDERAL, STATE, AND LOCAL LAWS, REGULATIONS, AND SIMILAR REQUIREMENTS.

Standard A

Licensing of Institution

In any State in which State or applicable local law provides for the licensing of extended care facilities, the institution (1) is licensed pursuant to such law, or (2) is approved by the agency of the State or locality responsible for licensing such institutions, as meeting the standards established for such licensing.

Standard B

Licensing of Staff

Staff of the extended care facility is currently licensed or registered in accordance with applicable laws.

Standard C

Conformity With Other Laws

The extended care facility is in conformity with laws relating to fire and safety, communicable and reportable diseases, and other relevant matters.

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Condition of Participation

II. ADMINISTRATIVE MANAGEMENT

THE EXTENDED CARE FACILITY HAS AN EFFECTIVE GOVERNING BODY* LEGALLY RESPONSIBLE FOR THE CONDUCT OF THE FACILITY, WHICH DESIGNATES AN ADMINISTRATOR AND ESTABLISHES ADMINISTRATIVE POLICIES.

Standard A

Governing Body

There is a governing body which assumes full legal responsibility for the overall conduct of the facility.

Factor 1. The ownership of the facility is fully disclosed to the State agency. In the case of corporations, the corporate officers are made known.

Factor 2. The governing body is responsible for compliance with the applicable laws and regulations of legally authorized agencies.

Standard B

Full-Time Administrator

The governing body appoints a full-time administrator who is qualified by training and experience and delegates to him the internal operation of the facility in accordance with established policies.

Factor 1. The administrator is at least 21 years old, capable of making mature judgments, and has no physical or mental disabilities or personality disturbances which interfere with carrying out his responsibilities.

Factor 2. It is desirable for the administrator to have a minimum of a high school education, to have completed courses in administration or management and to have had at least 1 year of work experience including some administrative experience in an extended care facility or related health program.

Factor 3. The administrator's responsibilities for procurement and direction of competent personnel are clearly defined.

Factor 4. An individual competent and authorized to act in the absence of the administrator is designated.

Factor 5. The administrator may be a member of the governing body.

Standard C

Personnel Policies

There are written personnel policies, practices and procedures that adequately support sound patient care.

Factor 1. Current employee records are maintained and include a résumé of each employee's training and experience.

Factor 2. Files contain evidence of adequate health supervision such as results of preemployment and periodic physical examinations, including chest X-rays, and records of all illnesses and accidents occurring on duty.

Factor 3. Work assignments are consistent with qualifications.

Standard D

Notification of Changes in Patient Status

There are appropriate written policies and procedures relating to notification of responsible persons in the event of significant change in patient status, patient charges, billings, and other related administrative matters.

Factor 1. Patients are not transferred or discharged without prior notification of next of kin or sponsor.

Factor 2. Information describing the care and services provided by the facility is accurate and not misleading.

duct of the extended care facility carry out or have carried out the functions herein pertaining to the governing body.

*If the extended care facility does not have an organized governing body, the person(s) legally responsible for the con-



Condition of Participation
III. PATIENT CARE POLICIES

THERE ARE POLICIES TO GOVERN THE SKILLED NURSING CARE AND RELATED MEDICAL OR OTHER SERVICES PROVIDED, WHICH ARE DEVELOPED WITH THE ADVICE OF PROFESSIONAL PERSONNEL, INCLUDING ONE OR MORE PHYSICIANS AND ONE OR MORE REGISTERED PROFESSIONAL NURSES.

Standard A

Policies Relating to Patient Care

The extended care facility has written policies which are developed with the advice of (and with provision for review of such policy from time to time by) a group of professional personnel, including at least one or more physicians and one or more registered professional nurses, to govern the skilled nursing care and related medical or other services it provides. Policies reflect awareness of and provision for meeting the total needs of patients. These are reviewed at least annually and cover at least the following:

- Admission, transfer, and discharge policies including categories of patients accepted and not accepted by the extended care facility.
- Physician services.
- Nursing services.
- Dietary services.
- Restorative services.
- Pharmaceutical services.
- Diagnostic services.
- Care of patients in an emergency, during a communicable disease episode, and when critically ill or mentally disturbed.
- Dental services.
- Social services.
- Patient activities.
- Clinical records.

- Transfer agreement.
- Utilization review.

Factor 1. It is desirable that the group of professional personnel responsible for patient-care policies includes health personnel such as social workers, dieticians, pharmacists, speech, physical and occupational therapists, and mental health personnel. Pharmacy policies and procedures are preferably developed with the advice of a subgroup of physicians and pharmacists, serving as a pharmacy and therapeutics committee.

Factor 2. Some members of this group are neither owners nor employees of the facility.

Factor 3. The group meets at regularly scheduled intervals and minutes of each meeting are recorded.

Factor 4. The group may serve one or more facilities.

Standard B

Responsibilities For Execution of Patient Care Policies

The extended care facility has a physician, a registered professional nurse, or a medical staff responsible for the execution of patient care policies established by the professional group referred to in standard A.

Factor 1. If the organized medical staff is responsible, an individual physician is designated to maintain compliance with overall patient care policies.

Factor 2. If a registered professional nurse is responsible, the facility makes available an advisory physician from whom she receives medical guidance.



Condition of Participation

IV. PHYSICIAN SERVICES

THE EXTENDED CARE FACILITY ADMITS PATIENTS IN NEED OF SKILLED NURSING CARE ONLY UPON THE RECOMMENDATION OF A PHYSICIAN; THEIR HEALTH CARE CONTINUES UNDER THE SUPERVISION OF A PHYSICIAN; AND THE FACILITY HAS A PHYSICIAN AVAILABLE TO FURNISH NECESSARY MEDICAL CARE IN CASE OF EMERGENCY.

Standard A

Medical Findings and Physicians Orders

There is made available to the facility, prior to or at the time of admission, patient information which includes current medical findings, diagnoses, rehabilitation potential, a summary of the course of treatment followed in the hospital, and orders from a physician for the immediate care of the patient.

Factor 1. If the above information is not available in the facility upon admission of the patient, it is obtained by the facility within 48 hours after admission.

Factor 2. If medical orders for the immediate care of a patient are unobtainable at the time of admission, the physician with responsibility for emergency care gives temporary orders.

Factor 3. A current hospital discharge summary containing the above information is acceptable.

Standard B

Supervision by Physician

The facility has a requirement that the health care of every patient is under the supervision of a physician who, based on an evaluation of the patient's immediate and long-term needs, prescribes a planned regimen of medical care which covers indicated medications, treatments, restorative services, diet, special procedures recommended for the health and safety of the patient, activities, and plans for continuing care and discharge.

Factor 1. The medical evaluation of the patient is based on a physical examination done within 48 hours of admission unless such examination was performed within 5 days prior to admission.

Factor 2. The charge nurse and other appropriate personnel involved in the care of the patient assists in planning his total program of care.

Factor 3. The patient's total program of care is reviewed and revised at intervals appropriate to his needs. Attention is given to special needs of patients such as foot, sight, speech, and hearing problems.

Factor 4. Orders concerning medications and treatments are in effect for the specified number of days indicated by the physician but in no case exceed a period of 30 days unless reordered in writing by the physician.

Factor 5. Telephone orders are accepted only when necessary and only by licensed nurses. Telephone orders are written into the appropriate clinical record by the nurse receiving them and are countersigned by the physician within 48 hours.

Factor 6. Patients are seen by a physician at least once every 30 days. There is evidence in the clinical record of the physician's visits to the patient at appropriate intervals.

Factor 7. There is evidence in the clinical record that the physician has made arrangements for the medical care of the patient in the physician's absence.

Factor 8. To the extent feasible, each patient or his sponsor designates a personal physician.

Standard C

Availability of Physicians for Emergency Care

The extended care facility provides for having one or more physicians available to furnish necessary medical care in case of emergency if the physician responsible for the care of the patient is not immediately available. A schedule listing the names and telephone numbers of these physicians and the specific days each is on call is posted in each nursing station.

Factor 1. There are established procedures to be followed in an emergency, which cover immediate care of the patient, persons to be notified, and reports to be prepared.



Condition of Participation

V. NURSING SERVICES

THE EXTENDED CARE FACILITY PROVIDES 24-HOUR NURSING SERVICE WHICH IS SUFFICIENT TO MEET THE NURSING NEEDS OF ALL PATIENTS. THERE IS AT LEAST ONE REGISTERED PROFESSIONAL NURSE EMPLOYED FULL TIME AND RESPONSIBLE FOR THE TOTAL NURSING SERVICE. THERE IS A REGISTERED PROFESSIONAL NURSE OR LICENSED PRACTICAL NURSE WHO IS A GRADUATE OF A STATE APPROVED SCHOOL OF PRACTICAL NURSING IN CHARGE OF NURSING ACTIVITIES DURING EACH TOUR OF DUTY.

Standard A

Full-Time Nurse

There is at least one registered professional nurse employed full time. If there is only one registered professional nurse, she serves as director of the nursing service, works full time during the day, and devotes full time to the nursing service of the facility. If the director of nursing has administrative responsibility for the facility, she has a professional nurse assistant so that there is the equivalent of a full-time director of nursing service.

Factor 1. The director of nursing service is trained or experienced in areas such as nursing service administration, rehabilitation nursing, psychiatric or geriatric nursing.

Standard B

Director of Nursing Service

The director of the nursing service is responsible for:

- Developing and/or maintaining nursing service objectives, standards of nursing practice, nursing procedure manuals, and written job descriptions for each level of nursing personnel;
- Recommending to the administrator the number and levels of nursing personnel to be employed, participating in their recruitment and selection, and recommending termination of employment when necessary;
- Assigning and supervising all levels of nursing personnel;
- Participating in planning and budgeting for nursing care;

- Participating in the development and implementation of patient care policies and bringing patient care problems requiring changes in policy to the attention of the professional policy advisory groups;
- Coordinating nursing services with other patient care services such as physician, physical therapy, occupational therapy, and dietary;
- Planning and conducting orientation programs for new nursing personnel, and continuing inservice education for all nursing personnel;
- Participating in the selection of prospective patients in terms of nursing services they need and nursing competencies available;
- Assuring that a nursing care plan is established for each patient and that his plan is reviewed and modified as necessary.

Standard C

Supervising Nurse

Nursing care is provided by or under the supervision of a full-time registered professional nurse currently licensed to practice in the State.

Factor 1. The supervising nurse is trained or experienced in areas such as nursing administration and supervision, rehabilitation nursing, psychiatric or geriatric nursing.

Factor 2. The supervising nurse makes daily rounds to all nursing units performing such functions as visiting each patient, reviewing clinical records, medication cards, patient care plans and staff assignments, and to the greatest degree possible accompanying physicians when visiting patients.

Standard D

Charge Nurse

There is at least one registered professional nurse or qualified licensed practical nurse who is a graduate of a State-approved school of practical nursing on duty at all times and in charge of the nursing activities during each tour of duty.

Factor 1. It is desirable that the nurse in charge of each tour of duty be trained or experienced in areas such as nursing administration and supervision, rehabilitation nursing, psychiatric or geriatric nursing.

Factor 2. The charge nurse has the ability to recognize significant changes in the condition of patients and to take necessary action.

Factor 3. The charge nurse is responsible for the total nursing care of patients during her tour of duty.

Standard E

24-Hour Nursing Service

There is 24-hour nursing service with a sufficient number of nursing personnel on duty at all times to meet the total needs of patients.

Factor 1. Nursing personnel include registered professional nurses, licensed practical nurses, aides, and orderlies.

Factor 2. The amount of nursing time available for patient care is exclusive of nonnursing duties.

Factor 3. Sufficient nursing time is available to assure that each patient:

- (i.) Receives treatments, medications and diet as prescribed;
- (ii.) Receives proper care to prevent decubiti and is kept comfortable, clean, and well groomed;
- (iii.) Is protected from accident and injury by the adoption of indicated safety measures;
- (iv.) Is treated with kindness and respect.

Factor 4. Licensed practical nurses, nurses aides, and orderlies are assigned duties consistent with their training and experience.

Standard F

Restorative Nursing Care

There is an active program of restorative nursing care directed toward assisting each patient to achieve and maintain his highest level of self care and independence.

Factor 1. Restorative nursing care initiated in the hospital is continued immediately upon admission to the extended care facility.

Factor 2. Nursing personnel are taught restorative nursing measures and practice them in their daily care of patients. These measures include:

- (i.) Maintaining good body alignment and proper positioning of bedfast patients;
- (ii.) Encouraging and assisting bedfast patients to change positions at least every 2 hours day and night to stimulate circulation, and prevent decubiti and deformities;
- (iii.) Making every effort to keep patients active and out of bed for reasonable periods of time, except when contraindicated by physicians' orders, and encouraging patients to achieve independence in activities of daily living by teaching self care, transfer, and ambulation activities;
- (iv.) Assisting patients to adjust to their disabilities, to use their prosthetic devices, and to redirect their interests if necessary;
- (v.) Assisting patients to carry out prescribed physical therapy exercises between visits of the physical therapist.

Factor 3. Consultation and instruction in restorative nursing available from State or local agencies are utilized.

Standard G

Dietary Supervision

Nursing personnel are aware of the dietary needs and food and fluid intake of patients.

Factor 1. Nursing personnel observe that patients are served diets as prescribed.

Factor 2. Patients needing help in eating are assisted promptly upon receipt of meals.

Factor 3. Adaptive self-help devices are provided to contribute to the patient's independence in eating.

Factor 4. Food and fluid intake of patients is observed and deviations from normal are reported to the charge nurse. Persistent unresolved problems are reported to the physician.

Standard H

Nursing Care Plan

There is a written nursing care plan for each patient based on the nature of illness, treatment

prescribed, long and short-term goals and other pertinent information.

Factor 1. The nursing care plan is a personalized, daily plan for individual patients. It indicates what nursing care is needed, how it can best be accomplished for each patient, how the patient likes things done, what methods and approaches are most successful, and what modifications are necessary to insure best results.

Factor 2. Nursing care plans are available for use by all nursing personnel.

Factor 3. Nursing care plans are reviewed and revised as needed.

Factor 4. Relevant nursing information from the nursing care plan is included with other medical information when patients are transferred.

Standard I

Inservice Educational Program

There is a continuing inservice educational program in effect for all nursing personnel in addition to a thorough job orientation for new

personnel. Skill training for nonprofessional nursing personnel begins during the orientation period.

Factor 1. Planned inservice programs are conducted at regular intervals for all nursing personnel.

Factor 2. All patient care personnel are instructed and supervised in the care of emotionally disturbed and confused patients, and are helped to understand the social aspects of patient care.

Factor 3. All patient care personnel are helped to understand the social aspects of patient care.

Factor 4. Skill training includes demonstration, practice, and supervision of simple nursing procedures applicable in the individual facility. It also includes simple restorative nursing procedures.

Factor 5. Orientation of new personnel includes a review of the procedures to be followed in emergencies.

Factor 6. Opportunities are provided for nursing personnel to attend training courses in restorative nursing and other educational programs related to the care of long-term patients.



Condition of Participation

VI. DIETARY SERVICES

THE DIETARY SERVICE* IS DIRECTED BY A QUALIFIED INDIVIDUAL AND MEETS THE DAILY DIETARY NEEDS OF PATIENTS.

Standard A

Dietary Supervision

A person designated by the administrator is responsible for the total food service of the facility. If this person is not a professional dietitian, regularly scheduled consultation from a professional dietitian or other person with suitable training is obtained.

Factor 1. A professional dietitian meets the American Dietetic Association's qualification standards.

Factor 2. Other persons with suitable training are graduates of baccalaureate degree programs with major studies in foods and nutrition.

Factor 3. The person in charge of the dietary service participates in regular conferences with the administrator and other supervisors of patient services.

Factor 4. This person makes recommendations concerning the quantity, quality, and variety of food purchased.

Factor 5. This person is responsible for the orientation, training, and supervision of food-service employees, and participates in their selection and in the formulation of pertinent personnel policies.

Factor 6. Consultation obtained from self-employed dietitians or dietitians employed in voluntary or official agencies is acceptable if provided on a frequent and regularly scheduled basis.

*NOTE.—An extended care facility which has a contract with an outside food management company may be found to meet this condition of participation provided the company has a dietitian who serves, as required by the scope and complexity of the service, on a full-time, part-time or consultant basis to the extended care facility, and provided the company maintains standards as listed herein and provides for continuing liaison with the medical and nursing staff of the extended care facility for recommendations on dietetic policies affecting patient care.

Standard B

Adequacy of Dietary Staff

A sufficient number of food-service personnel are employed and their working hours are scheduled to meet the dietary needs of the patients.

Factor 1. There are food-service employees on duty over a period of 12 or more hours.

Factor 2. Food-service employees are trained to perform assigned duties and participate in selected in-service education programs.

Factor 3. In the event food-service employees are assigned duties outside the dietary department, these duties do not interfere with the sanitation, safety, or time required for dietary work assignments.

Factor 4. Work assignments and duty schedules are posted.

Standard C

Hygiene of Dietary Staff

Food-service personnel are in good health and practice hygienic food handling techniques.

Factor 1. Food-service personnel wear clean washable garments, hair nets or clean caps, and keep their hands and fingernails clean at all times.

Factor 2. Routine health examinations at least meet local, State or Federal codes for food-service personnel. Where food handlers' permits are required, they are current.

Factor 3. Personnel having symptoms of communicable diseases or open infected wounds are not permitted to work.

Standard D

Adequacy of Diet

The food and nutritional needs of patients are met in accordance with physicians' orders and, to the extent medically possible, meet the dietary

allowances of the Food and Nutrition Board of the National Research Council* adjusted for age, sex, and activity.

Standard E

Therapeutic Diets

Therapeutic diets are prepared and served as prescribed by the attending physician.

Factor 1. Therapeutic diet orders are planned, prepared, and served with supervision or consultation from a qualified dietitian.

Factor 2. A current diet manual recommended by the State licensure agency is readily available to food-service personnel and supervisors of nursing service.

Factor 3. Persons responsible for therapeutic diets have sufficient knowledge of good values to make appropriate substitutions when necessary.

Standard F

Frequency and Quality of Meals

At least three meals or their equivalent are served daily, at regular times, with not more than a 14-hour span between a substantial evening meal and breakfast. Between-meal or bedtime snacks of nourishing quality are offered. If the "four or five meal a day" plan is in effect, meals and snacks provide nutritional value equivalent to the daily food guide previously described.

Standard G

Planning of Menus

Menus are planned in advance and food sufficient to meet the nutrition needs of patients is prepared as planned for each meal. When

*The following daily food guide for adults is based on these allowances:

Milk—two or more cups.

Meat group—two or more servings: Beef, veal, pork, lamb, poultry, fish, eggs; occasionally dry beans, nuts, or dry peas may be served as alternates.

Vegetable and fruit group—four or more servings:

A citrus fruit or other fruit and vegetable important for vitamin C.

A dark green or deep yellow vegetable for vitamin A, at least every other day.

Other vegetables and fruits including potatoes.

Bread and cereal group—four or more servings of whole grain, enriched or restored.

Other foods to round out meals and snacks, to satisfy individual appetites and provide additional calories.

changes in the menu are necessary, substitutions provide equal nutritive value.

Factor 1. Menus are written at least 1 week in advance. The current week's menu is in one or more accessible places in the dietary department for easy use by workers purchasing, preparing, and serving foods.

Factor 2. Menus provide a sufficient variety of foods served in adequate amounts at each meal. Menus are different for the same days of each week and are adjusted for seasonal changes.

Factor 3. Records of menus as served are filed and maintained for 30 days.

Factor 4. Supplies of staple foods for a minimum of a 1-week period and of perishable foods for a minimum of a 2-day period are maintained on the premises.

Factor 5. Records of food purchased for preparation are on file.

Standard H

Preparation of Food

Foods are prepared by methods that conserve nutritive value, flavor, and appearance, and are attractively served at the proper temperatures and in a form to meet individual needs.

Factor 1. A file of tested recipes, adjusted to appropriate yield, is maintained.

Factor 2. Food is cut, chopped, or ground to meet individual needs.

Factor 3. If a patient refuses foods served, substitutes are offered.

Factor 4. Effective equipment is provided and procedures established to maintain food at proper temperature during serving.

Factor 5. Table service is provided for all who can and will eat at a table including wheelchair patients.

Factor 6. Trays provided bedfast patients rest on firm supports such as over-bed tables. Sturdy tray stands of proper height are provided patients able to be out of bed.

Standard I

Maintenance of Sanitary Conditions

Sanitary conditions are maintained in the storage, preparation, and distribution of food.

Factor 1. Effective procedures for cleaning all equipment and work areas are followed consistently.

Factor 2. Dishwashing procedures and techniques are well developed, understood, and carried out in compliance with the State and local health codes.

Factor 3. Written reports of inspections by State or local health authorities are on file at the facility with notation made of action taken by the facility to comply with any recommendations.

Factor 4. Waste which is not disposed of by mechanical means is kept in leakproof nonabsorbent containers with close-fitting covers and is disposed of daily in a manner that will prevent transmission of disease, a nuisance, a breeding place for flies, or a feeding place

for rodents. Containers are thoroughly cleaned inside and out each time emptied.

Factor 5. Dry or staple food items are stored off the floor in a ventilated room not subject to sewage or waste-water backflow, or contamination by condensation, leakage, rodents, or vermin.

Factor 6. Handwashing facilities including hot and cold water, soap and individual towels, preferably paper towels, are provided in kitchen areas.

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Condition of Participation
VII. RESTORATIVE SERVICES

RESTORATIVE SERVICES ARE PROVIDED UNDER MEDICAL DIRECTION.

Standard A

Medical Direction

Restorative services, including modalities to be used, frequency, and anticipated goals, are prescribed by the physician and carried out under medical direction.

Standard B

Minimal Restorative Services

At a minimum, restorative nursing care designed to maintain function or improve the patient's ability to carry out the activities of daily living is provided by the extended care facility. (See Condition of Participation V, Nursing Services, Standard F, for details.)

Standard C

Services of Therapists

When an extended care facility provides restorative services beyond restorative nursing care, whether directly or through cooperative arrangements with appropriate agencies such as hospitals, rehabilitation centers, State or local health departments, or independently practicing therapists, these services are given or supervised by qualified therapists.

Factor 1. Physical therapy includes such services as:

- (i.) Assisting the physician in evaluating patients by applying diagnostic and prognostic muscle, nerve, joint, and functional ability tests;
- (ii.) Treating patients to relieve pain, develop or restore function, and maintain maximum performance, using physical means such as exercise, massage, heat, water, light, and electricity.

Factor 2. A physical therapist is a graduate of a program in physical therapy approved by the council on education of the American Medical Association in collaboration with the American Physical Therapy Association or its equivalent and, when applicable, is licensed or registered by the State.

Factor 3. Speech therapy includes such services as:

- (i.) Assisting the physician in evaluating patients to determine the type of speech or language disorder and the appropriate corrective therapy;
- (ii.) Providing rehabilitative services for speech and language disorders.

Factor 4. A speech therapist is certified by the American Speech and Hearing Association, or has completed the academic requirements and is in the process of accumulating the necessary supervised work experience required for certification.

Factor 5. Occupational therapy includes duties such as:

- (i.) Assisting the physician in evaluating the patient's level of function by applying diagnostic and prognostic tests;
- (ii.) Guiding the patient in his use of therapeutic creative and self-care activities for improving function.

Factor 6. An occupational therapist is registered by the American Occupational Therapy Association or is a graduate of a program approved by the council on medical education of the American Medical Association in collaboration with the American Occupational Therapy Association and is in the process of accumulating supervised clinical experience required for registration.

Factor 7. Other personnel providing restorative services are specially trained and work under professional supervision in accordance with accepted professional practices. For example, an occupational therapy assistant has successfully completed a training course approved by the American Occupational Therapy Association, is certified by that body as a certified occupational therapy assistant, and receives supervision from a qualified occupational therapist.

Factor 8. Qualified therapists collaborate with the facility's medical and nursing staff in developing the patient's total plan of care.

Factor 9. Therapists participate in the facility's in-service education programs.

Standard D

Ambulation and Therapeutic Equipment

Commonly used ambulation and therapeutic equipment necessary for the services offered is available for use in the facility.

Factor 1. Recommended ambulation equipment includes such items as parallel bars, hand rails, wheel chairs, walkers, walkerettes, crutches, and canes.

Factor 2. The therapists advise the administrator concerning the purchase, rental, storage, and maintenance of equipment and supplies.

Condition of Participation
VIII. PHARMACEUTICAL SERVICES

WHETHER DRUGS ARE GENERALLY PROCURED FROM A COMMUNITY PHARMACY OR STOCKED BY THE FACILITIES, THE EXTENDED CARE FACILITY HAS METHODS AND PROCEDURES FOR ITS PHARMACEUTICAL SERVICES THAT ARE IN ACCORD WITH ACCEPTED PROFESSIONAL PRACTICES.

Standard A

Procedures for Administration of Pharmaceutical Services

The extended care facility provides appropriate methods and procedures for the obtaining, dispensing, and administering of drugs and biologicals, developed with the advice of a staff pharmacist, a consultant pharmacist, or a pharmaceutical advisory committee which includes one or more licensed pharmacists.

Factor 1. If the extended care facility has a pharmacy department, a licensed pharmacist is employed to administer the pharmacy department.

Factor 2. If the facility does not have a pharmacy department, it has provision for promptly and conveniently obtaining required drugs and biologicals from community pharmacies.

Factor 3. If the facility has only a drug room where bulk drugs are stored:

- (i.) The consultant pharmacist is responsible for the control of all bulk drugs and maintains records of their receipt and disposition.
- (ii.) The consultant pharmacist dispenses drugs from the drug room, properly labels them and makes them available to appropriate licensed nursing personnel. Wherever possible, the pharmacist in dispensing drugs works from the prescriber's original order or a direct copy.
- (iii.) Provision is made for emergency withdrawal of medications from the drug room.

Factor 3. An emergency medication kit approved by the facility's group of professional personnel is kept readily available.

Standard B

Conformance With Physicians' Orders

All medications administered to patients are ordered in writing by the patient's physician.

Oral orders are given only to a licensed nurse, immediately reduced to writing, signed by the nurse and countersigned by the physician within 48 hours. Medications not specifically limited as to time or number of doses, when ordered, are automatically stopped in accordance with written policy approved by the physician or physicians responsible for advising the facility on its medical administrative policies.

Factor 1. The charge nurse and the prescribing physician together review monthly each patient's medications.

Factor 2. The patient's attending physician is notified of stop order policies and contacted promptly for renewal of such orders so that continuity of the patient's therapeutic regimen is not interrupted.

Factor 3. Medications are released to patients on discharge only on the written authorization of the physician.

Standard C

Administration of Medications

All medications are administered by licensed medical or nursing personnel in accordance with the Medical and Nurse Practice Acts of each State. Each dose administered is properly recorded in the clinical record.

Factor 1. The nursing station has readily available items necessary for the proper administration of medication.

Factor 2. In administering medications, medication cards or other State approved systems are used and checked against the physician's orders.

Factor 3. Medications prescribed for one patient are not administered to any other patient.

Factor 4. Self-administration of medications by patients is not permitted except for emergency drugs on

special order of the patient's physician or in a predischARGE program under the supervision of a licensed nurse.

Factor 5. Medication errors and drug reactions are immediately reported to the patient's physician and an entry thereof made in the patient's clinical record as well as on an incident report.

Factor 6. Up-to-date medication reference texts and sources of information are provided, such as ASHP Hospital Formulary and Physicians Desk Reference.

Standard D

Labeling and Storing Medications

Patients' medications are properly labeled and stored in a locked cabinet at the nurses' station.

Factor 1. The label of each patient's individual medication container clearly indicates the patient's full name, physician's name, prescription number, name and strength of drug, date of issue, expiration date of all time-dated drugs, and name, address, and telephone number of pharmacy issuing the drug. It is advisable that the manufacturer's name and the lot or control number of the medication also appear on the label.

Factor 2. Medication containers having soiled, damaged, incomplete, illegible, or makeshift labels are returned to the issuing pharmacist or pharmacy for re-labeling or disposal. Containers having no labels are destroyed in accordance with State and Federal laws.

Factor 3. The medications of each patient are kept and stored in their originally received containers and transferring between containers is forbidden.

Factor 4. Separately locked, securely fastened boxes (or drawers) within the medicine cabinet are provided for storage of narcotics, barbiturates, amphetamines, and other dangerous drugs.

Factor 5. Cabinets are well lighted and of sufficient size to permit storage without crowding.

Factor 6. Medications requiring refrigeration are kept in a separate, locked box within a refrigerator at or near the nursing station.

Factor 7. Poisons and medications for "external use only" are kept in a locked cabinet and separate from other medications.

Factor 8. Medications no longer in use are disposed of or destroyed in accordance with Federal and State laws and regulations.

Factor 9. Medications having an expiration date are removed from usage and properly disposed of after such date.

Standard E

Compliance With Laws Controlling Narcotics, Etc.

The extended care facility complies with all Federal and State laws relating to the procurement, storage, dispensing, administration, and disposal of narcotics, hypnotics, amphetamines, certain psychosomatic medications, and other legend drugs.

Factor 1. A narcotic record is maintained which lists on separate sheets for each type and strength of narcotic the following information: date, time administered, name of patient, dose, physician's name, signature of person administering dose, and balance.

Condition of Participation
IX. DIAGNOSTIC SERVICES

THE EXTENDED CARE FACILITY HAS AN ARRANGEMENT FOR OBTAINING REQUIRED CLINICAL LABORATORY, X-RAY AND OTHER DIAGNOSTIC SERVICES.

Standard A

Provision For Diagnostic Services

The extended care facility has provision for promptly and conveniently obtaining required clinical laboratory, X-ray and other diagnostic services from a physician's office, an eligible hospital's laboratory, or an independent laboratory eligible to provide these services in the health insurance program. If the facility provides its own diagnostic services, these meet the conditions established for certification of hospitals.

Factor 1. All diagnostic services are provided only on the request of a physician.

Factor 2. The physician is notified promptly of the test results.

Factor 3. Arrangements are made for the transportation of patients, if necessary, to and from the source of service.

Factor 4. Simple tests, such as those customarily done by nursing personnel for diabetic patients, may be done in the facility.

Factor 5. All reports are included in the clinical record.



Condition of Participation

X. DENTAL SERVICES

THE EXTENDED CARE FACILITY ASSISTS PATIENTS TO OBTAIN
REGULAR AND EMERGENCY DENTAL CARE.*

Standard A

Provision For Dental Care

Patients are assisted to obtain regular and emergency dental care.

Factor 1. An advisory dentist provides consultation, participates in in-service education, recommends policies concerning oral hygiene, and is available in case of emergency.

Factor 2. The extended care facility, when necessary, arranges for the patient to be transported to the dentist's office.

Factor 3. Nursing personnel assist the patient to carry out the dentist's recommendations.

*The services of dentists to individual patients are not included as a benefit in the basic hospital insurance program, and only certain oral surgery is included in the supplemental medical insurance program.



Condition of Participation

XI. SOCIAL SERVICES

SERVICES ARE PROVIDED TO MEET THE MEDICALLY RELATED SOCIAL NEEDS OF PATIENTS.

Standard A

Provision For Medically Related Social Needs

The medically related social needs of the patient are identified, and services provided to meet them, in admission of the patient, during the treatment and care in the facility, and in planning for his discharge.

Factor 1. As a part of the process of evaluating a patient's need for services in an extended care facility and whether the facility can offer appropriate care, emotional and social factors are considered in relation to medical and nursing requirements.

Factor 2. As soon as possible after admission, there is evaluation, based on medical, nursing, and social factors, of the probable duration of the patient's need for care and a plan is formulated and recorded for providing such care.

Factor 3. Where there are indications that financial help will be needed, arrangements are made promptly for referral to an appropriate agency.

Factor 4. Social and emotional factors related to the patient's illness, to his response to treatment, and to his adjustment to care in the facility are recognized and appropriate action is taken when necessary to obtain case-work services to assist in resolving problems in these areas.

Factor 5. Knowledge of the patient's home situation, financial resources, community resources available to assist him, and pertinent information related to his medical and nursing requirements are used in making decisions regarding his discharge from the facility.

Standard B

Staff Member Responsible

There is a designated member of the staff of the facility who will take responsibility, when medically related social problems are recognized, for action necessary to solve them.

Factor 1. There is a full time or part time social

worker employed by the facility, or there is a person on the staff who is suited by training and/or experience in related fields to find community resources to deal with the social problems.

Factor 2. The staff member responsible for this area of service has information promptly available on health and welfare resources in the community.

Factor 3. If the facility does not have a qualified social worker on its staff, there is an effective arrangement with a public or private agency, which may include the local welfare department, to provide social service consultation.

Factor 4. A qualified social worker is a graduate of a school of social work accredited by the council on social work education.

Standard C

Training of Staff

There is provision for orientation and in-service training of staff directed toward understanding emotional problems and social needs of sick and infirm aged persons, and recognition of social problems of patients and the means of taking appropriate action in relation to them.

Factor 1. Either a qualified social worker on the staff, or one from outside the facility, participates in training programs, case conferences, and arrangements for staff orientation to community services and patient needs.

Standard D

Confidentiality of Social Data

Pertinent social data, and information about personal and family problems related to the patient's illness and care, are made available only to the attending physician, appropriate members of the nursing staff, and other key personnel who are directly involved in the patient's care, or to recognize health or welfare agencies. There are appropriate policies and procedures for assuring the confidentiality of such information.

Factor 1. The staff member responsible for social services participates in clinical staff conferences and/or confers with the attending physician prior to admission of the patient, at intervals during the patient's stay in the facility, and prior to discharge of the patient, and there is evidence in the record of such conferences.

Factor 2. The staff member and nurses responsible for the patient's care confer frequently and there is

evidence of effective working relationships between them.

Factor 3. Records of pertinent social information, and of action taken to meet social needs, are maintained for each patient; signed social service summaries are entered promptly in the patient's clinical record for the benefit of all staff involved in the care of the patient.

Condition of Participation

XII. PATIENT ACTIVITIES

ACTIVITIES SUITED TO THE NEEDS AND INTERESTS OF PATIENTS ARE PROVIDED AS AN IMPORTANT ADJUNCT TO THE ACTIVE TREATMENT PROGRAM AND TO ENCOURAGE RESTORATION TO SELF CARE AND RESUMPTION OF NORMAL ACTIVITIES.

Standard A

Provision For Patient Activity

Provision is made for purposeful activities which are suited to the needs and interests of patients.

Factor 1. An individual is designated as being in charge of patient activities. This individual has experience and/or training in directing group activity, or has available consultation from a qualified recreational therapist or group activity leader.

Factor 2. The activity leader uses, to the fullest possible extent, community, social, and recreational opportunities.

Factor 3. Patients are encouraged, but not forced, to participate in such activities. Suitable activities are provided for patients unable to leave their rooms.

Factor 4. Patients who are able and who wish to do so are assisted to attend religious services.

Factor 5. Patients' requests to see their clergymen are honored and space is provided for privacy during visits.

Factor 6. Visiting hours are flexible and posted to permit and encourage visiting by friends and relatives.

Factor 7. The facility makes available a variety of supplies and equipment adequate to satisfy the individual interests of patients. Examples of such supplies and equipment are: books and magazines, daily newspapers, games, stationery, radio and television, and the like.



Condition of Participation

XIII. CLINICAL RECORDS

A CLINICAL RECORD IS MAINTAINED FOR EACH PATIENT ADMITTED, IN ACCORDANCE WITH ACCEPTED PROFESSIONAL PRINCIPLES.

Standard A

Maintenance of Clinical Record

The extended care facility maintains a separate clinical record for each patient admitted with all entries kept current, dated, and signed. The record includes:

- Identification and summary sheet(s) including patient's name, social security number, marital status, age, sex, home address, and religion; names, addresses, and telephone numbers of referral agency (including hospital from which admitted), personal physician, dentist, and next of kin or other responsible person; admitting diagnosis; final diagnosis, condition on discharge, and disposition, and any other information needed to meet State requirements;
- Initial medical evaluation including medical history, physical examination, diagnosis, and estimation of restoration potential;
- Authentication of hospital diagnoses, in the form of a hospital summary discharge sheet, or a report from the physician who attended the patient in the hospital, or a transfer form used under a transfer agreement;
- Physician's orders, including all medications, treatments, diet, restorative and special medical procedures required for the safety and well-being of the patient;
- Physician's progress notes describing significant changes in the patient's condition, written at the time of each visit;
- Nurse's notes containing observations made by the nursing personnel;
- Medication and treatment record including all medications, treatments, and special procedures performed for the safety and well-being of the patient;
- Laboratory and X-ray reports;

- Consultation reports;
- Dental reports;
- Social service notes;
- Patient care referral reports.

Standard B

Retention of Records

All clinical records of discharged patients are completed promptly and are filed and retained in accordance with State law or for 5 years in the absence of a State statute.

Factor 1. The extended care facility has policies providing for the retention and safekeeping of patients' clinical records by the governing body for the required period of time in the event that the extended care facility discontinues operation.

Factor 2. If the patient is transferred to another health care facility, a copy of the patient's clinical record or an abstract thereof accompanies the patient.

Standard C

Confidentiality of Records

All information contained in the clinical records is treated as confidential and is disclosed only to authorized persons.

Standard D

Staff Responsibility

If the extended care facility does not have a full- or part-time medical record librarian, an employee of the facility is assigned the responsibility for assuring that records are maintained, completed, and preserved.

Factor 1. The designated individual is trained by, and receives, regular consultation from a person skilled in record maintenance and preservation.

Condition of Participation
XIV. TRANSFER AGREEMENT

THE EXTENDED CARE FACILITY HAS IN EFFECT A TRANSFER AGREEMENT (MEETING THE REQUIREMENTS OF SECTION 1861(1) OF THE SOCIAL SECURITY ACT) WITH ONE OR MORE HOSPITALS WHICH HAVE ENTERED INTO AGREEMENTS WITH THE SECRETARY TO PARTICIPATE IN THE PROGRAM.*

Standard A
Patient Transfer

The transfer agreement provides reasonable assurance that transfer of patients will be effected between the hospital and the extended care facility whenever such transfer is medically appropriate as determined by the attending physician.

Factor 1. The agreement is with a hospital close enough to the facility to make the transfer of patients feasible.

Factor 2. The transfer agreement facilitates continuity of patient care and expedites appropriate care for the patient.

Factor 3. The agreement may be made on a one-to-one basis or on a community-wide basis. The letter arrangement could provide for a master agreement to be signed by each hospital and extended care facility.

Factor 4. When the transfer agreement is on a community-wide basis it reflects the mutual planning and agreement of hospitals, extended care facilities, and other related agencies.

Factor 5. The institutions provide to each other information about their resources sufficient to determine whether the care needed by a patient is available.

Factor 6. Where the transfer agreement specifies restrictions with respect to the types of services available in the hospital or the facility and/or the types of patients or health conditions that will not be accepted by the hospital or the facility, or includes any other criteria relating to the transfer of patients (such as priorities for persons on waiting lists), such restrictions or criteria are the same as those applied by the hospital or facility to all other potential inpatients of the hospital or facility.

*A transfer agreement may be considered to be in effect under the circumstances outlined in standard E.

Factor 7. When a transfer agreement has been in effect over a period of time, a sufficient number of patient transfers between the two institutions have occurred to indicate that the transfer agreement is effective.

Standard B
Interchange of Information

The transfer agreement provides reasonable assurance that there will be interchange of medical and other information necessary or useful in the care and treatment of individuals transferred between the institutions, or in determining whether such individuals can be adequately cared for otherwise than in either of such institutions.

Factor 1. The agreement establishes responsibility for the prompt exchange of patient information to enable each institution to determine whether it can adequately care for the patient and to assure continuity of patient care.

Factor 2. Medical information transferred includes current medical findings, diagnosis, rehabilitation potential, a brief summary of the course of treatment followed in the hospital or extended care facility, nursing and dietary information useful in the care of the patient, ambulation status, and pertinent administrative and social information.

Factor 3. The agreement provides for the transfer of personal effects, particularly money and valuables, and for the transfer of information related to these items.

Standard C
Execution of Agreement

The transfer agreement is in writing and is signed by individuals authorized to execute such an agreement on behalf of the institutions, or, in case the two institutions are under common con-

trol, there is a written policy or order signed by the person or body which controls them.

Factor 1. When the hospital and extended care facility are not under common control, the terms of the transfer agreement are established jointly by both institutions.

Factor 2. Each institution participating in the agreement maintains a copy of the agreement.

Standard D

Specification of Responsibilities

The transfer agreement specifies the responsibilities each institution assumes in the transfer of patients and information between the hospital and the extended care facility.

Factor 1. The agreement establishes responsibility for notifying the other institution promptly of the impending transfer of a patient; arranging for appropriate and safe transportation; and arranging for the care of patients during transfer.

Standard E

Presumed Agreement Where Necessary For Provision of Service

An extended care facility which does not have a transfer agreement in effect but which is found by the State agency conducting the survey (or, in case of a State in which there is no such agency,

by the Secretary) to have attempted in good faith to enter into a transfer agreement with a hospital sufficiently close to the facility to make feasible the transfer between them of patients and medical and other information, shall be considered to have such an agreement in effect if and for so long as it is also found that to do so is in the public interest and essential to assuring extended care services for patients in the community eligible for benefits.

Factor 1. If there is only one hospital in the community, the extended care facility has attempted in good faith to enter into a transfer agreement with that hospital.

Factor 2. If there are several hospitals in the community, the extended care facility has exhausted all reasonable possibilities of entering into a transfer agreement with these hospitals.

Factor 3. The extended care facility has copies of letters, records of conferences, and other evidence to support its claim that it has attempted in good faith to enter into a transfer agreement.

Factor 4. The State agency has found that hospitals in the community have, in fact, refused to enter into a transfer agreement with the extended care facility in question.

Factor 5. The State agency has taken into consideration the availability of extended care facilities in the community and the expected need of such services for eligible beneficiaries under the law.

Condition of Participation
XV. PHYSICAL ENVIRONMENT

THE EXTENDED CARE FACILITY IS CONSTRUCTED, EQUIPPED, AND MAINTAINED TO INSURE THE SAFETY OF PATIENTS AND PROVIDES A FUNCTIONAL, SANITARY, AND COMFORTABLE ENVIRONMENT.*

Standard A
Safety of Patients

The extended care facility is constructed, equipped, and maintained to insure the safety of patients. It is structurally sound and satisfies the following conditions:

- The facility complies with all applicable State and local codes governing construction.
- Fire resistance and flame-spread ratings of construction, materials, and finishes comply with current State and local fire protection codes and ordinances.
- Sprinklers are installed in all areas considered to have special fire hazards including but not limited to boilerrooms, trash rooms, and nonfire-resistant areas or buildings. In an extended care facility of two or more stories fire alarm systems providing complete coverage of the building are installed and inspected regularly. Fire extinguishers are conveniently located on each floor and in special hazard areas such as boilerrooms, kitchens, laundries and storage rooms. Fire regulations are prominently posted and carefully observed.
- Doorways, passageways, and stairwells are wide enough for easy evacuation of patients and are kept free from obstruction at all times. Corridors are equipped with firmly secured handrails on each side. Stairwells, elevators, and all vertical shafts with openings have fire doors kept normally in closed position. Exit facilities comply with State and local codes and regulations.
- Unless the facility is of fire-resistive construction, blind and nonambulatory or physically handicapped persons are not housed above the street level floor.

*These are guidelines to help State agencies to evaluate existing structures which do not meet Hill-Burton standards. They are to be applied to existing construction with discretion and in light of community need for service.

- Reports of periodic inspections of the structure by the fire-control authority having jurisdiction in the area are on file in the facility.
- The building is maintained in good repair and kept free of hazards such as those created by any damaged or defective parts of the building.
- No occupancies or activities undesirable to the health and safety of patients are located in the building or buildings of the extended care facility.

Standard B
Favorable Environment For Patients

The extended care facility is equipped and maintained to provide a functional, sanitary, and comfortable environment. Its electrical and mechanical systems (including water supply and sewage disposal) are designed, constructed, and maintained in accordance with recognized safety standards (see app. B) and comply with applicable State and local codes and regulations.

Factor 1. Lighting levels in all areas of the facility are adequate and void of high brightness, glare, and reflecting surfaces that produce discomfort. Lighting levels are in accordance with recommendations of the Illuminating Engineering Society. The use of candles, kerosene oil lanterns, and other open-flame methods of illumination is prohibited.

Factor 2. An emergency electrical service, which may be battery operated if effective for 4 or more hours, covers lights at nursing stations, telephone switchboard, night lights, exit and corridor lights, boilerroom, and the fire-alarm system.

Factor 3. The heating and air-conditioning systems are capable of maintaining adequate temperatures and providing freedom from drafts.

Factor 4. An adequate supply of hot water for patient use is available at all times. Temperature of hot water at plumbing fixtures used by patients is automatically regulated by control valves and does not exceed 110° F. (110 degrees Fahrenheit).

Factor 5. The facility is well ventilated through the use of windows, mechanical ventilation, or a combination of both. Rooms and areas which do not have outside windows and which are used by patients or personnel are provided with functioning mechanical ventilation to change the air on a basis commensurate with the type of occupancy.

Factor 6. All inside bathrooms and toilet rooms have forced ventilation to the outside.

Factor 7. Laundry facilities (when applicable) are located in areas separate from patient units and are provided with the necessary washing, drying, and ironing equipment.

Standard C

Elevators

Elevators are installed in the facility if patient bedrooms are located on floors above the street level.

Factor 1. Installation of elevators and dumbwaiters complies with all applicable codes.

Factor 2. Elevators are of sufficient size to accommodate a wheeled stretcher.

Standard D

Nursing Unit

Each nursing unit has at least the following basic service areas: Nurses' station, medicine storage and preparation area, space for storage of linen, equipment and supplies, and a utility room.

Factor 1. A nurses' call system registers calls at the nurses' station from each patient bed, patient toilet room, and each bathtub or shower.

Factor 2. Equipment necessary for charting and recordkeeping is provided.

Factor 3. The medication preparation area is well illuminated and is provided with hot and cold running water.

Factor 4. The utility room is located, designed, and equipped to provide areas for the separate handling of clean and soiled linen, equipment, and supplies.

Factor 5. Toilet and handwashing facilities are provided.

Standard E

Patients' Bedrooms and Toilet Facilities

Patients' bedrooms are designed and equipped for adequate nursing care and the comfort and privacy of patients. Each bedroom has or is conveniently located near adequate toilet and bathing facilities. Each bedroom has direct access to a corridor and outside exposure, with the floor at or above grade level.

Factor 1. Ordinarily rooms have no more than four beds with not less than 3 feet between beds.

Factor 2. In addition to basic patient care equipment each patient unit has a nurses' call signal, an individual reading light, bedside cabinet, comfortable chair, and storage space for clothing and other possessions. In multiple bedrooms, each bed has flameproof-cubicle curtains or their equivalent.

Factor 3. It is desirable that each patient room have a lavatory with both hot and cold running water, unless provided in adjacent toilet or bathroom facilities.

Factor 4. On floors where wheelchair patients are located, there is at least one toilet room large enough to accommodate wheelchairs.

Factor 5. Each bathtub or shower is in a separate room or compartment which is large enough to accommodate wheelchair and attendant.

Factor 6. At least one water closet, enclosed in a separate room or stall, is provided for each eight beds.

Factor 7. Substantially secured grab bars are installed in all water closet and bathing fixture compartments.

Factor 8. Doors to patient bedrooms are never locked.

Standard F

Facilities For Isolation

Provision is made for isolating infectious patients in well-ventilated single bedrooms having separate toilet and bathing facilities. Such facilities are also available to provide for the special care of patients who develop acute illnesses while in the facility and patients in terminal phases of illness.

Standard G

Examination Rooms

A special room (or rooms) is provided for examinations, treatments, and other therapeutic procedures.

Factor 1. This room is of sufficient size and is equipped with a treatment table, lavatory or sink with

other than hand controls, instrument sterilizer, instrument table, and necessary instruments and supplies.

Factor 2. If the facility provides physical therapy, areas are of sufficient size to accommodate necessary equipment and facilitate the movement of disabled patients. Lavatories and toilets designed for the use of wheelchair patients are provided in such areas.

Standard H

Dayroom and Dining Area

The extended care facility provides one or more attractively furnished multipurpose areas of adequate size for patient dining, diversional, and social activities.

Factor 1. At least one dayroom or lounge, centrally located, is provided to accommodate the diversional and social activities of the patients. In addition, several smaller dayrooms, convenient to patient bedrooms, are desirable.

Factor 2. Dining areas are large enough to accommodate all patients able to eat out of their rooms. These areas are well lighted and well ventilated.

Factor 3. If a multipurpose room is used for dining and diversional and social activities, there is sufficient space to accommodate all activities and prevent their interference with each other.

Standard I

Kitchen or Dietary Area

The extended care facility has a kitchen or dietary area adequate to meet food service needs and arranged and equipped for the refrigeration, storage, preparation, and serving of food as well as for dish and utensil cleaning and refuse storage and removal. Dietary areas comply with the local health or food handling codes.

Factor 1. Food preparation space is arranged for the separation of functions and is located to permit efficient service to patients and is not used for nondietary functions.

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Condition of Participation

XVI. HOUSEKEEPING SERVICES

THE EXTENDED CARE FACILITY PROVIDES THE HOUSEKEEPING AND MAINTENANCE SERVICES NECESSARY TO MAINTAIN A SANITARY AND COMFORTABLE ENVIRONMENT.

Standard A

Housekeeping Services

The facility provides sufficient housekeeping and maintenance personnel to maintain the interior and exterior of the facility in a safe, clean, orderly, and attractive manner. Nursing personnel are not assigned housekeeping duties.

Factor 1. Housekeeping personnel, using accepted practices and procedures, keep the facility free from offensive odors, accumulations of dirt, rubbish, dust, and safety hazards.

Factor 2. Floors are cleaned regularly. Polishes on floors provide a nonslip finish; throw or scatter rugs are not used except for nonslip entrance mats.

Factor 3. Walls and ceilings are maintained free from cracks and falling plaster, and are cleaned and painted regularly.

Factor 4. Deodorizers are not used to cover up odors caused by unsanitary conditions or poor housekeeping practices.

Factor 5. Storage areas, attics, and cellars are kept safe and free from accumulations of extraneous materials such as refuse, discarded furniture, and old newspapers. Combustibles such as cleaning rags and compounds are kept in closed metal containers.

Factor 6. The grounds are kept free from refuse and litter. Areas around buildings, sidewalks, gardens, and patios are kept clear of dense undergrowth.

Standard B

Pest Control

The facility is maintained free from insects and rodents.

Factor 1. A pest-control program is in operation in the facility. Pest-control services are provided by

maintenance personnel of the facility or by contract with a pest-control company. Care is taken to use the least toxic and least flammable effective insecticides and rodenticides. These compounds are stored in nonpatient areas and in nonfood preparation and storage areas. Poisons are under lock.

Factor 2. Windows and doors are appropriately screened during the insect breeding season.

Factor 3. Harborage and entrances for insects and rodents are eliminated.

Factor 4. Garbage and trash are stored in areas separate from those used for the preparation and storage of food and are removed from the premises in conformity with State and local practices. Containers are cleaned regularly.

Standard C

Linen

The facility has available at all times a quantity of linen essential for the proper care and comfort of patients. Linens are handled, stored, and processed so as to control the spread of infection.

Factor 1. The linen supply is at least three times the usual occupancy.

Factor 2. Clean linen and clothing are stored in clean, dry, dust-free areas easily accessible to the nurses' station.

Factor 3. Soiled linen is stored in separate well-ventilated areas, and is not permitted to accumulate in the facility. Soiled linen and clothing are stored separately in suitable bags or containers.

Factor 4. Soiled linen is not sorted, laundered, rinsed, or stored in bathrooms, patient rooms, kitchens, or food storage areas.



Condition of Participation

XVII. DISASTER PLAN

THE EXTENDED CARE FACILITY HAS A WRITTEN PROCEDURE TO BE FOLLOWED IN CASE OF FIRE OR OTHER DISASTER.

Standard A

Disaster Plan

The facility has a written procedure to be followed in case of fire, explosion, or other emergency. It specifies persons to be notified, locations of alarm signals and fire extinguishers, evacuation routes, procedures for evacuating helpless patients, frequency of fire drills, and assignment of specific tasks and responsibilities to the personnel of each shift.

Factor 1. The plan is developed with the assistance of qualified fire and safety experts.

Factor 2. All personnel are trained to perform assigned tasks.

Factor 3. Simulated drills testing the effectiveness of the plan are conducted on each shift at least three times a year.

Factor 4. The plan is posted throughout the facility.

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UTILIZATION REVIEW PLAN

Introduction

The discussion of the utilization review provisions in the congressional committee reports clearly indicate that the intent of Congress was to provide a flexible framework within which extended care facilities, in cooperation with physicians, hospitals, State health departments and other community organizations, could develop the most appropriate and effective utilization review procedures for such facilities. The conditions, standards, and factors relating to utilization review in extended care facilities have, therefore, been designed so as to assure that there will be sufficient latitude for extended care facilities to develop and implement a variety of patterns of utilization review. Since it is recognized that utilization review in extended care facilities is a relatively unexplored area, and that extended care facilities vary widely with respect to their size, organization, and location, many different types of utilization review plans will fulfill the requirements of the law and the regulations.

Extended care facilities wishing to establish their eligibility to participate will be required to submit a written description of their utilization review plan and a certification that it is in effect or that it will be in effect on January 1, 1967. Ordinarily, this will constitute sufficient evidence to support a finding that the utilization review plan of the extended care facility is or is not conformity with the statutory requirements.

Intermediaries and State agencies will be relied on heavily to participate with the medical profession and the administrative staff of extended care facilities in long-run measures to assure that utilization review operates effectively.

The review plan of an extended care facility should have as its overall objectives the maintenance of high quality patient care, more effective utilization of extended care services (through the mechanism of an educational approach involving study of patterns of care), and the encouragement of appropriate utilization. It is contemplated that a review of the medical necessity of admissions and duration of stays, for example, would take into account alternative use and availability of other facilities and services.

The review of professional services furnished might include study of such conditions as overuse or underuse of services, proper use of consultation, and whether the required nursing and related care is initiated and carried out promptly. Review of lengths of stay might consider not only medical necessity, but whether assistance is available to the physician in arranging for discharge planning, and the availability of other facilities and services which will assure continuity of care.

Costs incurred in connection with the implementation of the utilization review plan are includible in reasonable costs and are reimbursable to the extent that such costs relate to health insurance program beneficiaries.

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Condition of Participation

XVIII. UTILIZATION REVIEW PLAN

THE EXTENDED CARE FACILITY HAS IN EFFECT A PLAN FOR UTILIZATION REVIEW WHICH APPLIES AT LEAST TO THE SERVICES FURNISHED BY THE FACILITY TO INDIVIDUALS ENTITLED TO BENEFITS UNDER THE LAW. AN ACCEPTABLE UTILIZATION REVIEW PLAN PROVIDES FOR: (1) THE REVIEW ON A SAMPLE OR OTHER BASIS, OF ADMISSIONS, DURATION OF STAYS, AND PROFESSIONAL SERVICES FURNISHED; AND (2) REVIEW OF EACH CASE OF CONTINUOUS EXTENDED DURATION.

Standard A

Development and Approval

The operation of the utilization review plan is a responsibility of the medical profession. The plan for reviewing utilization in the facility is developed with the advice of the facility's group of professional personnel referred to in Condition of Participation III, and has the approval of the facility's medical staff, if any, and the facility's governing body.

Standard B

Description of Plan

The extended care facility has a currently applicable, written description of its utilization review plan. Such description includes:

- The organization and composition of the committee(s) which will be responsible for the utilization review functions;
- Frequency of meetings;
- The type of records to be kept;
- The method to be used in selecting cases on a sample or other basis;
- The definition of what constitutes the period or periods of extended duration;
- The relationship of the utilization review plan to claims administration by a third party;
- Arrangements for committee reports and their dissemination;
- Responsibilities of the facility's administrative staff in support of utilization review.

Standard C

Composition of Committee

The utilization review function is conducted

by one or a combination of the following (except that with respect to facilities lacking an organized medical staff, review is conducted only as in the second or third paragraph below):

- ***By a staff committee of the facility, which is composed of two or more physicians, with or without the inclusion of other professional personnel; or***
- ***By a committee(s) or group(s) outside the facility composed as in the paragraph above which is established by the local medical society and some or all of the hospitals and extended care facilities in the locality; or***
- ***Where a committee(s) or group(s) as described in the first or second paragraph above has not been established to carry out all the utilization review functions prescribed by the act, by a committee(s) or group(s) composed as in the first paragraph above, and sponsored and organized in such manner as approved by the Secretary of Health, Education, and Welfare.***

Factor 1. The medical care appraisal and educational aspects of review on a sample or other basis, and the review of long-stay cases need not be done by the same committee or group.

Factor 2. In a facility with an organized medical staff, all of the review functions may be carried out in the facility by a committee of the whole or a medical care appraisal committee.

Factor 3. The committee(s) includes at least one member who does not have a direct financial interest in the institution.

Factor 4. Under the final paragraph of this standard, any sponsorship of a utilization committee or group is

ordinarily acceptable if it is composed as in the first paragraph of this standard.

Standard D

Reviews on Sample or Other Basis

Reviews are made, on a sample or other basis, of admissions, duration of stays, and professional services (including drugs and biologicals) furnished, with respect to the medical necessity of the services, and for the purpose of promoting the most efficient use of available health facilities and services. Such reviews emphasize identification and analysis of patterns of patient care in order to maintain consistent high quality. The review is accomplished by considering the data obtained by any one or any combination of the following:

- By use of services and facilities of external organizations which compile statistics, design profiles, and produce other comparative data; or
- By cooperative endeavor with the intermediary or State agency; or
- By studies of medical records of patients of the institution.

Factor 1. Some review functions are carried out on a continuing basis.

Factor 2. Reviews include a sample of physician recertifications of medical necessity for extended care facility services, as made for purposes of the Health Insurance for the Aged Program.

Standard E

Reviews of Extended Duration Cases

Reviews are made of each beneficiary case of continuous extended duration. The extended care facility's utilization review plan specifies the number of continuous days of stay in the extended care facility following which a review is made to determine whether further inpatient extended care services are medically necessary. The plan may specify a different number of days for different classes of cases.

Reviews for such purpose are made no later than the seventh day following the last day of the period of extended duration specified in the plan. No physician has review responsibility for any case of continuous extended duration in which he was professionally involved.

If physician members of the committee decide, after opportunity for consultation is given the at-

tending physician by the committee, and considering the availability and appropriateness of other facilities and services, that further inpatient stay is not medically necessary, there is to be prompt notification (within 48 hours) in writing to the facility, the physician responsible for the patient's care, and the patient or his representative.

Factor 1. Because there are significant divergences in opinion among individual physicians with respect to evaluation of medical necessity for posthospital extended care services, the judgment of the attending physician in an extended stay case is given great weight, and is not rejected except under unusual circumstances.

Standard F

Maintenance and Use of Records

Records are kept of the activities of the committee; and reports are regularly made by the committee to the executive committee of the medical staff (if any) or to the facilities, institutions, and organizations sponsoring the utilization review plan, and relevant information and recommendations are reported through usual channels to the entire medical staff and the governing body of the facility, and the sponsor of the plan.

Factor 1. The extended care facility administration studies and acts upon administrative recommendations made by the utilization review committee.

Factor 2. A summary of the number and types of cases reviewed, and the findings, are part of the records of the committee and the participating facilities and institutions.

Factor 3. Minutes of each committee meeting are maintained.

Factor 4. Committee action in extended stay cases is recorded, with cases identified only by case number when possible.

Standard G

Staff Cooperation With Review Committee

The committee(s) having responsibility for utilization review functions have the support and assistance of the facility's administrative staff in assembling information, facilitating chart reviews, conducting studies, exploring ways to improve procedures, maintaining committee records, and promoting the most efficient use of available health services and facilities.

Factor 1. With respect to each of these activities, an individual or department is designated as being responsible for the particular service.

Factor 2. In order to encourage the most efficient use of available health services and facilities, assistance to the physician in timely planning for care following extended facility care is initiated as promptly as possible,

either by the facility's staff, or by arrangement with other agencies. For this purpose, the facility makes available to the attending physician current information on resources available for continued noninstitutional or custodial care of patients and arranges for prompt transfer of appropriate medical and nursing information in order to assure continuity of care upon discharge of a patient.

APPENDIX A
EXCERPTS FROM PUBLIC LAW 89-97

The following excerpts from Public Law 89-97 define extended care services and facilities.

Section 1861(h). The term "extended care services" means the following items and services furnished to an inpatient of an extended care facility and (except as provided in pars. (3) and (6)) by such extended care facility:

- (1) Nursing care provided by or under the supervision of a registered professional nurse;
- (2) Bed and board in connection with the furnishing of such nursing care;
- (3) Physical, occupational, or speech therapy furnished by the extended care facility or by others under arrangements with them made by the facility;
- (4) Medical social services;
- (5) Such drugs, biologicals, supplies, appliances, and equipment, furnished for use in the extended care facility, as are ordinarily furnished by such facility for the care and treatment of inpatients;
- (6) Medical services provided by an intern or resident-in-training of a hospital with which the facility has in effect a transfer agreement (meeting the requirements of subsec. (1)), under a teaching program of such hospital approved as provided in the last sentence of subsection (b) and other diagnostic or therapeutic services provided by a hospital with which the facility has such an agreement in effect; and
- (7) Such other services necessary to the health of the patients as are generally provided by extended care facilities; excluding, however, any item or service if it would not be included under subsection (b) if furnished to an inpatient of a hospital.

Section 1861(j). The term "extended care facility" means (except for purposes of subsec. (a) (2)) an institution (or a distinct part of an institution) which has in effect a transfer agreement (meeting the requirements of subsec. (1)) with one or more hospitals having agreements in effect under section 1866 and which:

- (1) Is primarily engaged in providing to inpatients (A) skilled nursing care and related services for patients who require medical or nursing care, or (B) rehabilitation services for the rehabilitation of injured, disabled, or sick persons;
- (2) Has policies, which are developed with the advice of (and with provision of review of such policies

from time to time by) a group of professional personnel, including one or more physicians and one or more registered professional nurses, to govern the skilled nursing care and related medical or other services it provides;

- (3) Has a physician, a registered professional nurse, or a medical staff responsible for the execution of such policies;

- (4) (A) Has a requirement that the health care of every patient must be under the supervision of a physician, and (B) provides for having a physician available to furnish necessary medical care in case of emergency;

- (5) Maintains clinical records on all patients;

- (6) Provides 24-hour nursing service which is sufficient to meet nursing needs in accordance with the policies developed as provided in paragraph (2), and has at least one registered professional nurse employed full time;

- (7) Provides appropriate methods and procedures for the dispensing and administering of drugs and biologicals;

- (8) Has in effect a utilization review plan which meets the requirements of subsection (k);

- (9) In the case of an institution in any State in which State or applicable local law provides for the licensing of institutions of this nature, (A) is licensed pursuant to such law, or (B) is approved, by the agency of such State or locality responsible for licensing institutions of this nature, as meeting the standards established for such licensing; and

- (10) Meets such other conditions relating to the health and safety of individuals who are furnished services in such institution or relating to the physical facilities thereof as the Secretary may find necessary (subject to the second sentence of sec. 1863); except that such term shall not (other than for purposes of subsection (a) (2)) include any institution which is primarily for the care and treatment of mental diseases or tuberculosis. For purposes of subsection (a) (2), such term includes any institution which meets the requirements of paragraph (1) of this subsection. The term "extended care facility" also includes an institution described in paragraph (1) of subsection (y), to the

extent and subject to the limitation provided in such subsection.

Section 1361(1). A hospital and an extended care facility shall be considered to have a transfer agreement in effect if, by reason of a written agreement between them or (in case the two institutions are under common control) by reason of a written undertaking by the person or body which controls them, there is reasonable assurance that:

(1) Transfer of patients will be effected between the hospital and the extended care facility whenever such transfer is medically appropriate as determined by the attending physician; and

(2) There will be interchange of medical and other information necessary or useful in the care and treatment of individuals transferred between the institutions, or in determining whether such individuals can be ade-

quately cared for otherwise than in either of such institutions.

Any extended care facility which does not have such an agreement in effect, but which is found by a State agency (of the State in which such facility is situated) with which an agreement under section 1364 is in effect (or, in the case of a State in which no such agency has an agreement under section 1364, by the Secretary) to have attempted in good faith to enter into such an agreement with a hospital sufficiently close to the facility to make feasible the transfer between them of patients and the information referred to in paragraph (2), shall be considered to have such an agreement in effect if and for so long as such agency (or the Secretary, as the case may be) finds that to do so is in the public interest and essential to assuring extended care services for persons in the community who are eligible for payments with respect to such services under this title.

APPENDIX B

SELECTED NATIONAL CODES AND STANDARDS

Appropriate national codes and standards are to be followed when applicable city, county, or State codes, ordinances, and regulations are not in effect.

1. National Building Code
National Board of Fire Underwriters,
85 John Street,
New York, N.Y. 10038
2. Recommendations of the
American Society of Mechanical Engineers,
29 West 39th Street,
New York, N.Y. 10018
3. Heating Ventilating Air-Conditioning Guide
American Society of Heating, Refrigerating, and Air-Conditioning Engineers,
Inc.
234 Fifth Avenue,
New York, N.Y. 10001
4. Building Exits Code
National Electrical Code
Other National Fire Codes and Codes for Medical Gases
National Fire Protection Association,
60 Batterymarch Street,
Boston, Mass. 02110
5. National Plumbing Code A.S.A.—A 40.8
Specifications for "Making Buildings and Facilities Accessible to, and Usable by,
the Physically Handicapped"—A117.1
American Standard Safety Code for Elevators, Dumbwaiters, and Escalators—
A17.1
American Standards Association,
70 East 45th Street,
New York, N.Y. 10017



APPENDIX C

**Extended Care Facility Request To Establish Eligibility in
the Health Insurance for the Aged Program
Instructions for Completing the Form**



EXTENDED CARE FACILITY REQUEST TO ESTABLISH ELIGIBILITY IN THE HEALTH INSURANCE FOR THE AGED PROGRAM

All extended care facilities desiring to establish their eligibility in the health insurance program should complete this form and return it to the State agency that is handling the certification process. If a return envelope is not provided, the name and address of the State agency may be obtained from the nearest Social Security Administration district office.

SUBMISSION OF THIS FORM AND ESTABLISHING ELIGIBILITY DOES NOT OBLIGATE AN EXTENDED CARE FACILITY TO PARTICIPATE. AN AGREEMENT WILL BE MADE AVAILABLE BY THE SOCIAL SECURITY ADMINISTRATION AT A LATER DATE TO EXTENDED CARE FACILITIES WHO HAVE ESTABLISHED ELIGIBILITY. THERE IS NO COMMITMENT UNTIL THE AGREEMENT IS SIGNED.

Form Approved.
Budget Bureau No. 72-R727

DO NOT WRITE IN THIS SPACE
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DATE CERTIFIED
CERTIFICATION

I. Identifying Information	A. NAME OF FACILITY		STREET ADDRESS	
	CITY, COUNTY, AND STATE		ZIP CODE	TELEPHONE NUMBER (Including area code)
	NAME OF CHIEF ADMINISTRATIVE OFFICER		TITLE	
	B. NAME AND ADDRESS OF PARENT INSTITUTION (If applicable)			
II. Licensure	1 <input type="checkbox"/> Licensed or approved as _____ by a state or local government agency. Name of agency.		LICENSE EFFECTIVE BEGINNING DATE THRU DATE 2 <input type="checkbox"/> No license or approval required	
III. Transfer Agreement	A. Does the facility have a written agreement in effect with any hospital for the transfer of patients and medical and other information between the institutions? 1 <input type="checkbox"/> Yes (If "Yes," please attach a copy of the written agreement) 2 <input type="checkbox"/> No (If "No," complete B below) B. Has an attempt been made to enter into such an agreement? 1 <input type="checkbox"/> Yes (If "Yes," please attach a description of attempts made to enter into an agreement) 2 <input type="checkbox"/> No			
IV. Utilization Review Plan	Does the extended care facility have a Utilization Review Plan in effect at present? 1 <input type="checkbox"/> Yes 2 <input type="checkbox"/> No (If "Yes," Utilization Review to be made by): 1 <input type="checkbox"/> Committee(s) of Extended Care 2 <input type="checkbox"/> Group outside the Extended Facility Medical Staff Care Facility established by Local Medical Staff 3 <input type="checkbox"/> Other			
PLEASE ATTACH A COPY OR TENTATIVE DESCRIPTION OF YOUR UTILIZATION REVIEW PLAN, IF AVAILABLE.				

V. Mental or TB	Is the facility primarily for the care of patients with tuberculosis or mental disease?	
	1 <input type="checkbox"/> Yes	2 <input type="checkbox"/> No
VI. Nursing	A. Does the facility provide 24-hour nursing service?	B. Is at least one registered professional nurse employed full time?
	1 <input type="checkbox"/> Yes	2 <input type="checkbox"/> No

ITEMS VII THRU XII ARE FOR STATISTICAL PURPOSES

VII. Type of Facility (Check one)	1 <input type="checkbox"/> Skilled Nursing Facility 3 <input type="checkbox"/> Extended Care Unit of Rehabilitation Center 5 <input type="checkbox"/> Other (Specify) _____ 2 <input type="checkbox"/> Extended Care Unit of Hospital 4 <input type="checkbox"/> Extended Care Unit of Domiciliary Institution		
VIII. Type of Control (Check one)	Voluntary Non-Profit 1 <input type="checkbox"/> Church 2 <input type="checkbox"/> Other (Specify) _____ Proprietary 3 <input type="checkbox"/>	Government (Non-Federal) 4 <input type="checkbox"/> State 6 <input type="checkbox"/> City 5 <input type="checkbox"/> County 7 <input type="checkbox"/> City-County Other 8 <input type="checkbox"/> Specify _____	
IX. Facilities and Services Provided (Check all applicable)	01 <input type="checkbox"/> Nursing 06 <input type="checkbox"/> Recreational Activities 11 <input type="checkbox"/> Dentistry* 02 <input type="checkbox"/> Physical Therapy 07 <input type="checkbox"/> Pharmacy 12 <input type="checkbox"/> Podiatry* 03 <input type="checkbox"/> Occupational Therapy 08 <input type="checkbox"/> Clinical Laboratory 13 <input type="checkbox"/> Ophthalmology* 04 <input type="checkbox"/> Speech Therapy 09 <input type="checkbox"/> X-Ray, Diagnostic 14 <input type="checkbox"/> Other (Specify) _____ 05 <input type="checkbox"/> Social Services 10 <input type="checkbox"/> Examination and Treatment Room *Generally not covered under Title XVIII of the Social Security Act.		
X. Physicians	NUMBER OF PHYSICIANS ON THE MEDICAL STAFF		
XI. Number of Employees (Full-Time Equivalents)	A. REGISTERED PROFESSIONAL NURSES	B. LICENSED PRACTICAL NURSES	C. QUALIFIED PHYSICAL THERAPISTS
	D. QUALIFIED OCCUPATIONAL THERAPISTS	E. QUALIFIED SPEECH THERAPISTS	F. LICENSED PHARMACISTS
	G. QUALIFIED SOCIAL WORKERS	H. OTHER SOCIAL WORK PERSONNEL	I. ALL OTHERS
XII. Bed Capacity	A. TOTAL BEDS		B. NUMBER OF NURSING BEDS

SIGNATURE OF AUTHORIZED OFFICIAL

TITLE

DATE

INSTRUCTIONS FOR COMPLETING EXTENDED CARE FACILITY REQUEST TO ESTABLISH ELIGIBILITY IN THE HEALTH INSURANCE FOR THE AGED PROGRAM (SSA-1516)

The filing of this request for eligibility will initiate the process of obtaining a decision as to whether the Conditions of Participation are met. An extended care facility that establishes its eligibility may later enter into an agreement to become a participating extended care facility.

Submission of this form and establishing eligibility does not obligate an extended care facility to participate. An agreement will be made available by the Social Security Administration at a later date to extended care facilities who have established eligibility. There is no commitment until the agreement is signed.

Please do not delay returning the form, even though certain information is not now available (e.g., the transfer agreement or the utilization review plan has not been completed). Assistance in filling out the form is available from the State agency.

General Instructions

Please answer all questions as of the current date.

Return the original and first copy to the State agency in the envelope provided; retain the second copy for your files. If a return envelope is not provided, the name and address of the State agency may be obtained from the nearest Social Security Administration district office.

Detailed Instructions for Specific Questions

These instructions are designed to clarify certain questions on the form. Instructions are listed in question order for easy reference. No instructions have been given for questions considered self-explanatory.

Question I—Identifying Information

- A. Insert the full name under which the extended care facility operates.
- B. If the facility is a component or subunit of a larger institution such as a hospital, provide the name and address of the parent institution.

Question III—Transfer Agreement

- A. Check Yes if there is a written agreement (or a written policy where the facility and a hospital are under common control) in effect between the facility and any hospital providing for the transfer of patients and medical and other information between the institutions.
- B. Include in the description of attempts made to enter into an agreement:
 1. Name and address of hospital(s) contacted; and
 2. Dates hospital(s) contacted.

Note: PLEASE DO NOT DELAY SENDING YOUR REQUEST TO THE STATE AGENCY IF YOU DO NOT HAVE A WRITTEN TRANSFER AGREEMENT IN EFFECT OR A UTILIZATION REVIEW PLAN. It is recognized that some extended care facilities may require additional time or may need to seek consultation in setting up an agreement or developing a utilization review plan. The extended care facility should arrange to enter into a transfer agreement and complete its utilization review plan as far in advance of January 1, 1967 as is possible. The State agency will be glad to consult with you concerning the timing and method of fulfilling these requirements. The agreement and plan should comply with the requirements as stated in the Conditions of Participation for Extended Care Facilities.

Question VII—Type of Facility

Check the one category most descriptive of your facility's predominant type of care.

1. *Skilled Nursing Facility*—an institution which has as its primary objective providing skilled nursing and related services.
3. *Extended Care Unit of Rehabilitation Center*—a distinct part of a rehabilitation institution where skilled nursing and related services are provided.
4. *Extended Care Unit of Domiciliary Institution*—a distinct part of an institution for custodial care where skilled nursing and related services are provided.

Question VIII—Type of Control

Check the one category that is most descriptive of the type of organization operating the extended care facility.

Question IX—Facilities and Services Provided

Check the facilities that are available on the premises and the services normally provided to patients. (Check the services available to patients even though they are not currently being provided.)

Question XI—Number of Employees

Include only those personnel regularly employed. Include members of religious orders. Exclude all trainees, private-duty nurses, and volunteers. To arrive at full-time equivalents, add the total number of hours worked by all employees in each classification in the week ending prior to the week of filing the request and divide by the number of hours in the standard work week. If the result for each classification is not

a whole number, express it as a fraction (e.g., $2\frac{1}{4}$).

Include in the count of *qualified physical therapists* only those physical therapists who are graduates of a program in physical therapy approved by the Council on Education of the American Medical Association in collaboration with the American Physical Therapy Association or its equivalent, and, when applicable, are licensed or registered by the State.

Include in the count of *qualified occupational therapists* only those occupational therapists who are registered by the American Occupational Therapy Association or are graduates of a program approved by the Council on Medical Education of the American Medical Association and are in the process of accumulating supervised clinical experience required for registration.

Include in the count of *qualified speech therapists* only those speech therapists who are certified by the

American Speech and Hearing Association or have completed the academic requirements and are in the process of accumulating the necessary supervised work experience required for certification.

Include in the count of *qualified social workers* only those social workers who are graduates of a school of social work accredited by the Council on Social Work Education.

Question XII—Bed Capacity

- A. Show only the total number of beds, including custodial beds, in the skilled nursing facility or extended care unit.
- B. Show only the number of beds available for patients receiving skilled nursing care. (Do *not* include custodial beds.)









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CONDITIONS FOR COVERAGE OF SERVICES OF INDEPENDENT LABORATORIES



U.S. DEPARTMENT OF
HEALTH, EDUCATION, AND WELFARE
SOCIAL SECURITY ADMINISTRATION

HIM-4 (3-66)

U.S. Bureau of Health Insurance



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CONDITIONS FOR COVERAGE OF SERVICES OF INDEPENDENT LABORATORIES

Introduction

The Conditions for Coverage of Services of Independent Laboratories and related policies set forth herein, which will be reflected in regulations of the Department of Health, Education, and Welfare, state the specific requirements that must be met by an independent laboratory in order for its services to qualify for reimbursement under the supplementary medical insurance part of the health insurance for the aged program.

Definition of Independent Laboratory

An independent laboratory performing diagnostic tests is one which is independent both of the attending physician's office and of a hospital which meets the conditions of participation in the program. "The laboratory a physician maintains for performing diagnostic tests in connection with his own practice would be exempt from . . . [the prescribed] standards but if the physician runs a laboratory which performs diagnostic work referred by other physicians the laboratory would be subject to these standards." (Report on H.R. 6675 of the Senate Committee on Finance, p. 43.) Services furnished by out-of-hospital laboratories under the direction of a physician, such as a pathologist or radiologist, are considered to be subject to the conditions where the physician holds himself out to the general public and/or other physicians as being available primarily for the performance of diagnostic X-ray and/or other laboratory services.

Section 1861(s) of the Social Security Act, which includes the provision for the coverage in the medical insurance program of diagnostic tests performed in an independent laboratory, provides that, as a condition for coverage of such tests, an independent laboratory, in any State in which State or local law provides for licensing laboratories, is licensed pursuant to such law or is approved by the agency of the State or locality responsible for such licensure as meeting the standards established for licensing. As a further condition, the statute requires that the independent laboratory meet such standards as the Secretary of Health, Education, and Welfare finds necessary to assure the health and safety of individuals with respect to whom these tests are performed.

The law makes provision for the designation of State health agencies, or other State agencies, to assist the Department in determining whether there is compliance with the conditions for coverage of services of inde-

pendent laboratories. The designated State agencies will certify to the Department of Health, Education, and Welfare those laboratories which meet the conditions. Services provided in a laboratory that is found to be in substantial compliance with the conditions relating to health and safety and which meet the statutory licensure requirement would be reimbursable under the medical insurance program.

Simultaneously with the release of these materials to interested individuals, organizations, and agencies, the Department is proceeding with the necessary action to establish conforming regulations. The official Notice of Proposed Rule Making and of the opportunity for submission of data, comments, and arguments relating to the proposed regulations is being provided in accordance with the regular procedure of publication in the Federal Register.

Conditions for Coverage of Services

In the preparation of the conditions for coverage of services, there has been extensive discussion and consultation with organizations and experts in the fields of radiology, clinical laboratory services, and medical care. Groups consulted included, among others, representatives of State agencies, American Medical Association, College of American Pathologists, American College of Radiology, American Chemical Society, and American Association of Bioanalysts. The conditions have also been reviewed and concurred in by the Health Insurance Benefits Advisory Council, the statutory body established for the purpose of advising the Secretary on matters of general policy in the administration of this program and in the formulation of applicable regulations.

The conditions have been developed in accordance with the requirements, authorizations, and limitations of the law. The services of an independent laboratory will be reimbursable under the program only if the laboratory meets the statutory requirement of section 1861(s) (10) and there has been a finding of substantial compliance on the part of the laboratory with all the other conditions. These additional conditions (established in the interest of health and safety) are requirements which are essential to the maintenance of quality of care and the adequacy of the services and facilities which the laboratory provides. Variations in the type and size of laboratories and the nature and scope of

services offered will be reflected in differences in the details of organization, staffing, and facilities. However, the test will be whether there is substantial compliance with each of the conditions.

As a basis for a determination as to whether or not there is substantial compliance with the prescribed conditions in the case of any particular independent laboratory, a series of standards, almost all interpreted by explanatory factors, is listed under each condition. Reference to these standards will enable the State agency surveying a facility to document the activities of the laboratory, to establish the nature and extent of its deficiencies, if any, and to assess the facility's need for improvement in relation to the prescribed conditions. In substance, the application of the standards, together with the explanatory factors, will indicate the extent and degree to which an independent laboratory is complying with each condition.

Under the Health Insurance for the Aged Act, State agencies, operating under an agreement with the Secretary, will be used by the Department in determining whether independent laboratories meet the conditions. Pursuant to this agreement, State agencies will certify to the Department findings as to whether independent laboratories are in substantial compliance with the conditions. Such certifications will include findings as to whether each of the conditions is substantially met. The Department, on the basis of such certification from the State agency, will determine whether or not the level of facilities and services of the laboratory represent the required achievement of substantial compliance with the conditions.

Principles for the Evaluation of Independent Laboratories to Determine Whether They Are in Substantial Compliance with the Conditions

Independent laboratories will be considered in substantial compliance with the conditions upon acceptance by the Secretary of findings, adequately documented and certified to by the State agency, showing that:

- A. The laboratory meets the specific statutory requirement of section 1861(s) (10) and is found to be operating in accordance with all the conditions with no significant deficiencies, or
- B. The laboratory meets the specific statutory requirement of section 1861(s) (10) but is found to have deficiencies with respect to one or more conditions, but
 1. It is making reasonable plans and efforts to correct the deficiencies, and
 2. Notwithstanding the deficiencies, it is rendering adequate service without hazard to the health and safety of individuals being served, taking into

account special procedures or precautionary measures which have been or are being instituted.

Time Limitations on Certification of Substantial Compliance

All initial certifications by the State agency to the effect that an independent laboratory is in substantial compliance with the conditions will be for a period of 1 year, beginning with July 1, 1966, or, if later, with the date on which the laboratory is first found to be in substantial compliance with the conditions. State agencies may visit or resurvey laboratories where necessary to ascertain continued compliance or to accommodate to periodic or cyclical survey programs. A State may, at any time, find and certify to the Secretary that a laboratory is no longer in compliance.

If a laboratory is certified by the State agency as in substantial compliance under the provisions of paragraph B., above, the following information will be incorporated into the finding and into the notice to the laboratory of the coverage of its services under the medical insurance program:

- A. A statement of the deficiencies which were found, and
- B. A description of progress which has been made and further action which is being taken to remove the deficiencies, and
- C. A scheduled time for a resurvey of the laboratory to be conducted not later than the ninth month (or earlier, depending on the nature of the deficiencies) of the period of certification.

Certification of Noncompliance

The State agency will certify that a laboratory is not in compliance with the conditions or, where a determination of compliance has been made, that a laboratory is no longer in compliance where:

- A. The laboratory is not in compliance with the statutory requirement of section 1861(s) (10), or
- B. The laboratory has deficiencies of such character as to seriously limit the capacity of the laboratory to render adequate service or to place health and safety of individuals in jeopardy, and the State agency concludes after discussion with the laboratory that there is no early prospect of such significant improvement as to establish substantial compliance, or
- C. After a previous period or part thereof for which the laboratory was certified with a finding of significant deficiencies, there is a lack of progress toward a removal of deficiencies which the State agency finds are adverse to the health and safety of individuals being served.

Criteria for Determining Substantial Compliance

Findings made by a State agency as to whether an independent laboratory is in substantial compliance with the conditions require a thorough evaluation of the laboratory. The State evaluation will take into consideration:

- A. The degree to which each standard, as well as the total set of standards relating to a condition, is met;
- B. When there is a deficiency, whether the deficiency creates a serious hazard to health and safety; and
- C. Whether the laboratory is making reasonable plans and efforts to correct the deficiency within a reasonable period.

Documentation of Findings

The findings of the State agency with respect to each of the conditions should be adequately documented. Where the State agency certifies to the Department of Health, Education, and Welfare that a laboratory is not in compliance with the conditions, such documentation should include a report of any discussions concerning the deficiencies, a report of the laboratory's responses with respect to such discussions, and the State agency's assessment of the prospects for such improvements as to enable the laboratory to achieve substantial compliance with the conditions.



Condition for Coverage

I. COMPLIANCE WITH STATE AND LOCAL LAWS

THE LABORATORY IS IN CONFORMITY WITH ALL APPLICABLE
STATE AND LOCAL LAWS.

Standard A

Licensure.

The laboratory, in any State in which State or applicable local law provides for the licensing of laboratories, (1) is licensed pursuant to such law, or (2) is approved, by the agency of the State or locality responsible for licensing laboratories, as meeting the standards established for such licensing.

Standard B

Licensed Staff.

The director and the staff of the laboratory are licensed or registered in accordance with applicable laws.

Standard C

Fire and Safety.

The laboratory is in conformity with laws relating to fire and safety, and to other relevant matters.



CLINICAL LABORATORY

DEFINITION:

A clinical laboratory is an independent laboratory (as previously defined) where microbiological, serological, chemical, hematological, biophysical, cytological, immunohematology, or pathological examinations are performed on materials derived from the human body, to provide information for the diagnosis, prevention or treatment of a disease or assessment of a medical condition.



Condition for Coverage

II. LABORATORY DIRECTOR

THE CLINICAL LABORATORY IS UNDER THE DIRECTION OF A QUALIFIED PERSON.

Standard A

Administration.

The laboratory has a director who administers the technical and scientific operation of the laboratory including the reporting of findings of laboratory tests.

Factor 1. The director serves the laboratory full-time, or on a regular part-time basis. If he serves on a regular part-time basis, (a) he does not individually serve as director of more than two laboratories (hospital or independent) or, (b) he provides an associate, qualified under Standard B following, to serve as assistant director in each laboratory. Such assistant director does not serve more than two laboratories.

Factor 2. Commensurate with the laboratory workload, the director spends an adequate amount of time daily in the laboratory to direct and supervise the technical performance of the staff.

Factor 3. The director is responsible for the proper performance of all tests made in the laboratory.

Factor 4. The director is responsible for the employment of qualified laboratory personnel and their inservice training.

Factor 5. If the director is to be continuously absent for more than one month, arrangements are made for a qualified substitute director.

Standard B

Laboratory Director—Qualification.

The laboratory director meets one of the following requirements:

1. He is a physician certified in anatomical and/or clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology, or possesses qualifications which are equivalent to those required for such certification.
2. He is a physician who (a) is certified by the American Board of Pathology or the American Osteopathic Board of Pathology in at least one of the laboratory specialties, or (b) is certified by the American Board of Microbiology, the American Board of Clinical Chemistry, or other national accrediting board acceptable to the Secretary in

- one of the laboratory specialties, or (c) subsequent to graduation has had four or more years of general laboratory training and experience, of which at least two were spent acquiring proficiency in one of the laboratory specialties in a clinical laboratory—with a director at the doctoral level—of a hospital, a health department, university, or medical research institution, or in the case of a State which regulates clinical laboratory personnel, in a clinical laboratory acceptable to that State.
3. He holds an earned degree of Doctor of Science or Doctor of Philosophy from an accredited institution¹ with a chemical, physical, or biological science as his major subject, and (a) is certified by the American Board of Microbiology, the American Board of Clinical Chemistry, or other national accrediting board acceptable to the Secretary in one of the laboratory specialties or, (b) subsequent to graduation, has had 4 or more years of general clinical laboratory training and experience, of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties in a clinical laboratory—with a director at the doctoral level—of a hospital, a health department, university, or medical research institution, or in the case of a State which regulates clinical laboratory personnel, in a clinical laboratory acceptable to that State.
 4. For a period ending June 30, 1971, an exception to these requirements may be made if (a) the director was responsible for the direction of a clinical laboratory on January 1, 1966, and (b) the State agency has evidence of successful participation of the laboratory which he directs in a State or State approved proficiency testing program covering the specialties or subspecialties in which the laboratory performs tests, and (c) the director holds at least a bachelor's degree from an accredited institution with a chemical, physical, or biological science as his major subject and subsequent to graduation has had at least 6 years of pertinent clinical laboratory experience.

¹“Accredited,” as used herein, refers to accreditation by a nationally recognized accrediting agency or association, as determined by the United States Commissioner of Education.



Condition for Coverage

III. SUPERVISION

THE CLINICAL LABORATORY IS SUPERVISED BY QUALIFIED PERSONNEL.

Standard A

Supervision.

The laboratory has one or more supervisors who, under the general direction of the laboratory director, supervise technical personnel and reporting of findings, perform tests requiring special scientific skills, and, in the absence of the director, are held responsible for the proper performance of all laboratory procedures.

Factor 1. Depending upon the size and functions of the laboratory, the laboratory director may also serve as the laboratory supervisor.

Factor 2. The supervisor serves the laboratory on a regular full-time basis.

Factor 3. The supervisor supervises and performs tests only in those laboratory specialties or subspecialties in which he is qualified by education, training and experience.

Standard B

Supervisor—Qualification.

The laboratory supervisor meets one of the following requirements:

1. He (a) is a physician or has earned a doctoral degree from an accredited institution with a chemical, physical, or biological science as his major subject and (b) subsequent to graduation has had at least 2 years experience in one of the laboratory specialties in a clinical laboratory—with a director at the doctoral level—of a hospital, a health department, university, or medical research institution, or in the case of a State which regulates clinical laboratory personnel, in a clinical laboratory acceptable to that State.
2. He holds a degree of master of arts or master of science from an accredited institution with a major in one of the chemical, physical, or biological sciences and, subsequent to graduation, has had at least 4 years of pertinent laboratory experience of which not less than 2 years has been spent working in the designated laboratory specialty in a clinical laboratory—with a director at

the doctoral level—of a hospital, a health department, university, or medical research institution, or in the case of a State which regulates clinical laboratory personnel, in a clinical laboratory acceptable to that State.

3. He holds a degree of bachelor of arts or bachelor of science from an accredited institution with a major in one of the chemical, physical, or biological sciences and, subsequent to graduation (a) has had at least 6 years of pertinent laboratory experience of which not less than 2 years has been spent working in the designated laboratory specialty in a clinical laboratory—with a director at the doctoral level—of a hospital, a health department, university, or medical research institution, or in the case of a State which regulates clinical laboratory personnel, in a clinical laboratory acceptable to that State; and (b) has successfully completed pertinent courses in an accredited college or university which, when combined with the foregoing experience, will provide technical and professional knowledge comparable to that of 2 above.
4. He is registered as a clinical laboratory technologist by the American Society of Clinical Pathologists, MT(ASCP), the National Registry of Microbiologists, or other professionally sponsored national registry acceptable to the Secretary which maintains standards equivalent to the foregoing, and (a) has had at least 6 years of pertinent laboratory experience of which not less than 2 years has been spent working in the designated laboratory specialty in a clinical laboratory—with a director at the doctoral level—of a hospital, university, health department, or medical research institution or in the case of a State which regulates clinical laboratory personnel, in a clinical laboratory acceptable to that State; and (b) has successfully completed pertinent courses in an accredited college or university which, when combined with the foregoing experience, will provide a technical and professional knowledge comparable to that of 2 above.



Condition for Coverage

IV. TESTS PERFORMED

THE CLINICAL LABORATORY PERFORMS ONLY THOSE LABORATORY TESTS AND PROCEDURES THAT ARE WITHIN THE SPECIALTIES IN WHICH THE LABORATORY DIRECTOR OR SUPERVISORS ARE QUALIFIED.

Standard A

Procedures and Tests—Competency.

The laboratory performs only those laboratory procedures and tests that are within the specialties or subspecialties in which the laboratory director or supervisors are qualified.

Factor 1. If the laboratory director or supervisor is a pathologist certified in both anatomical and clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possesses qualifications which are equivalent to those required for certification, the laboratory may perform laboratory procedures and tests in all specialties.

Factor 2. If neither the director nor supervisor has the qualifications described in Factor 1, and the laboratory performs tests in the specialty of microbiology, including the subspecialties of bacteriology, serology, virology, mycology and parasitology, the laboratory engages the services of a qualified director or supervisor, as defined previously, who (a) holds an earned doctoral or master's degree in microbiology from an accredited institution, or is a physician and (b) subsequent to graduation has had at least 4 years' experience in clinical microbiology.

Factor 3. If Factor 1 is not met and the laboratory perform tests in the specialty of immunohematology, including the subspecialties of blood groupings and RH typing, it engages the services of a qualified director or supervisor, as defined previously, who is a physician with at least 2 years' experience in clinical hematology subsequent to graduation.

Factor 4. If Factor 1 is not met and the laboratory performs tests in the specialty of hematology, including gross and microscopic examination of the blood,

it employs a qualified director or supervisor, as defined previously, who holds a master's or bachelor's degree in biology, immunology, or microbiology from an accredited institution and subsequent to graduation has had at least 4 years' experience in hematology.

Factor 5. If Factor 1 is not met and the laboratory performs tests in the specialty of clinical chemistry, it engages the services of a qualified director or supervisor, as defined previously, who (a) holds an earned doctoral or master's degree in chemistry or biochemistry from an accredited institution or is a physician, and (b) subsequent to graduation has had at least 4 years' experience in clinical chemistry.

Factor 6. If Factor 1 is not met and the laboratory performs tests in the specialty of tissue pathology then it engages the services of a pathologist who is certified in anatomical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possesses qualifications which are equivalent to those required for certification.

Factor 7. If Factor 1 is not met and the laboratory performs tests in the specialty of exfoliative cytology, it engages the services of a physician who: (a) is certified by the American Board of Pathology or the American Osteopathic Board of Pathology, or possesses qualifications which are equivalent to those required for certification or (b) is a member of the American Society of Cytology.

Factor 8. The laboratory whose director qualifies under Condition for Coverage II, Standard B, 4, may perform tests in the laboratory specialties in which such director is specifically qualified by training and experience. It performs tests in other laboratory specialties only if the director or supervisor meets the appropriate requirements of 1 to 7 above.



Condition for Coverage

V. TECHNICAL PERSONNEL

THE CLINICAL LABORATORY HAS A SUFFICIENT NUMBER OF PROPERLY QUALIFIED TECHNICAL PERSONNEL FOR THE VOLUME AND DIVERSITY OF TESTS PERFORMED.

Standard A

Technologist—Duties.

The laboratory employs a sufficient number of clinical laboratory technologists to proficiently perform under general supervision the clinical laboratory tests which require the exercise of independent judgment.

Factor 1. The clinical laboratory technologists perform tests which require the exercise of independent judgment and responsibility, with minimal supervision by the director or supervisors, in only those specialties or subspecialties in which they are qualified by education, training, and experience.

Factor 2. With respect to specialties in which the clinical laboratory technologist is not qualified by education, training, or experience, he functions only under direct supervision and performs only tests which require limited technical skill and responsibility.

Factor 3. Clinical laboratory technologists are in sufficient number to adequately supervise the work of technicians and trainees.

Standard B

Technologist—Qualifications.

Each clinical laboratory technologist possesses a current license as a clinical laboratory technologist issued by the State, if such licensing exists, and meets one of the following requirements:

1. He holds a degree of bachelor of arts or bachelor of science from an accredited institution with a major in one of the chemical, physical, or biological sciences and (a) has been employed for at least 1 year as a clinical laboratory technician or trainee in a clinical laboratory—with a director at the doctoral level—of a hospital, health department, university, or medical research institution, or in the case of a State which regulates clinical laboratory personnel, in a clinical laboratory acceptable to that State; or (b) has successfully completed at least 1 year of clinical laboratory internship as part of his college curriculum.

2. He is registered by (a) the American Society of Clinical Pathologists as a medical technologist, MT(ASCP), or as a clinical laboratory specialist or, (b) the National Registry of Microbiologists or, (c) other professionally sponsored national registry acceptable to the Secretary which maintains standards equivalent to (a) and (b) above.

Standard C

Technician—Duties.

Clinical laboratory technicians are employed in sufficient number to meet the workload demands of the laboratory and they function only under direct supervision of a clinical laboratory technologist.

Factor 1. Each clinical laboratory technician performs only those laboratory procedures which require limited technical skill and responsibility and a minimal exercise of independent judgment.

Factor 2. No one with lesser qualifications than a clinical laboratory technician performs laboratory procedures, although manual and clerical supplemental services may be rendered by others.

Factor 3. No clinical laboratory technician performs tests in the absence of a clinical laboratory technologist.

Standard D

Technician—Qualifications.

Each clinical laboratory technician possesses a current license as a clinical laboratory technician issued by the State, if such licensing exists, and meets one of the following requirements:

1. He has successfully completed 60 semester hours in an accredited college including the following courses: general chemistry, 1 year; biology or microbiology, 1 year.
2. He is a high school graduate and subsequent to graduation has served 2 years as a technician trainee in a clinical laboratory with a director at the doctoral level, or in the case of a State which

regulates clinical laboratory personnel, in a clinical laboratory acceptable to that State.

Standard E

Collection of Specimens.

No person other than a licensed physician or one otherwise authorized by law manipulates a patient for the collection of specimens, except that qualified technical personnel of the laboratory may collect blood or remove stomach contents and collect material for smears and culture under the direction, or upon the written request, of a licensed physician.

Standard F

Personnel policies.

There are written personnel policies, practices,

and procedures that adequately support sound laboratory practice.

Factor 1. Current employee records are maintained and include a resume of each employee's training and experience.

Factor 2. Files contain evidence of adequate health supervision of employees, such as results of pre-employment and periodic physical examinations, including chest X-rays, and records of all illnesses and accidents occurring on duty.

Factor 3. Work assignments are consistent with qualifications.

Factor 4. There is a program for employee orientation.

Condition for Coverage

VI. RECORDS, EQUIPMENT AND FACILITIES

THE CLINICAL LABORATORY MAINTAINS RECORDS, EQUIPMENT, AND FACILITIES WHICH ARE ADEQUATE AND APPROPRIATE FOR THE SERVICES OFFERED.

Standard A

Laboratory Management.

Space, facilities, and equipment are adequate to properly perform the services offered by the laboratory.

Factor 1. There is an adequate quality control program in effect including the use, where applicable, of reference or control sera and other biological samples, concurrent calibrating standards, and control charts recording standard readings.

Factor 2. All equipment is in good working order, routinely checked, and precisely calibrated.

Factor 3. Work bench space is ample, well-lighted, and convenient to sink, water, gas, suction, and electrical outlets as necessary.

Factor 4. The laboratory is properly ventilated.

Factor 5. Notebooks of appropriate current laboratory methods are available.

Factor 6. Adequate fire precautions are observed.

Factor 7. There is freedom from unnecessary physical, chemical, and biological hazards.

Standard B

Sterilization.

Syringes, needles, lancets, or other blood letting devices capable of transmitting infection from one person to another are not reused unless they are sterilized prior to each use, after first having been wrapped or covered in a manner which will insure that they remain sterile until the next use.

Factor 1. Each sterilizing cycle contains an indicator device which assures proper sterilization.

Standard C

Examination and Reports.

The laboratory examines specimens only at the request of a licensed physician, dentist, or other person authorized by law to use the find-

ings of laboratory examinations and reports only to those authorized by law to receive such results.

Factor 1. If the patient is sent to the laboratory, a written request for the desired laboratory procedures is obtained from a person authorized by law to use findings of laboratory examinations.

Factor 2. If only a specimen is sent, it is accompanied by a written request.

Factor 3. If the laboratory receives reference specimens from another laboratory it may report back to the laboratory submitting the specimens.

Standard D

Specimens—Records.

The laboratory maintains a record indicating the daily accession of specimens each of which is numbered or otherwise appropriately identified.

Factor 1. Records contain the following information:

- (a) The laboratory number or other identification of the specimen.
- (b) The name and other identification of the person from whom the specimen was taken.
- (c) The name of the licensed physician or other authorized person or clinical laboratory who submitted the specimen.
- (d) The date the specimen was collected by the physician or other authorized person.
- (e) The date the specimen was received in the laboratory.
- (f) The condition of unsatisfactory specimens when received (e.g., broken, leaked, hemolyzed or turbid, etc.).
- (g) The type of test performed.
- (h) The result of the laboratory test or cross reference to results and the date of reporting.

Standard E

Laboratory Report and Record.

The original laboratory report is sent promptly to the licensed physician or other authorized person who requested the test and a suitable record of each test result is preserved by the laboratory in accordance with the State's statutes of limitations.

Factor 1. The laboratory director is responsible for the laboratory report.

Factor 2. Duplicate copies or a suitable record of laboratory reports are filed in the laboratory in a manner which permits ready identification and accessibility.

Factor 3. Tissue pathology reports utilize acceptable terminology of a recognized system of disease nomenclature.

Factor 4. The results of laboratory tests or procedures or transcript thereof are not sent to the patient concerned except with the written consent of the physician or other authorized person who requested the test.

RADIOLOGY AND/OR NUCLEAR MEDICAL ISOTOPE LABORATORIES

DEFINITION:

A radiology and/or nuclear medical isotope laboratory is any independent laboratory (as previously defined) where ionizing radiation is used for diagnostic purposes. The term nuclear medical isotope laboratory refers to laboratories in which radioactive isotopes are applied to, injected in, or ingested by patients for diagnostic purposes.



Condition for Coverage

VII. DIRECTION OF LABORATORY AND INTERPRETATION OF PROCEDURES

THE RADIOLOGY AND/OR NUCLEAR MEDICAL ISOTOPE LABORATORY IS DIRECTED BY A QUALIFIED PHYSICIAN AND PROVIDES FOR THE INTERPRETATION OF PROCEDURE RESULTS.

Standard A

Administration.

The laboratory has a director who administers the technical and scientific operation of the laboratory.

Factor 1. The director serves the laboratory full time, or he may serve the laboratory on a regular part-time basis. If he serves on a regular part-time basis, (a) he does not individually serve as director of more than two laboratories or, (b) he provides a qualified associate to serve as assistant director in each laboratory. Such assistant director does not serve more than two laboratories.

Factor 2. The director is responsible for assuring that all roentgenologic and/or radioisotope procedures are properly performed and that the operation of radiographic equipment and use of radioactive materials are limited to qualified personnel.

Factor 3. The director spends an adequate amount of time each week in the laboratory to direct and supervise the technical performance of the staff.

Factor 4. If the director is not full time, or if the size of staff makes it necessary, the director designates a supervisor whom he deems qualified for this position to supervise laboratory personnel and perform procedures requiring special skills. The supervisor works under the general direction of the director.

Factor 5. The director is ultimately responsible for the employment of personnel who are qualified for the positions for which they are hired, and for assuring that they comply with applicable Federal and State standards pertaining to personnel who conduct procedures involving the use of ionizing radiation for diagnostic purposes.

Factor 6. If the director is to be continuously absent for more than 1 month, arrangements are made for a qualified substitute director.

Standard B

Director—Qualification.

The director is a physician licensed to practice

medicine in the State and is qualified by training and experience in the use of x rays and/or radioactive materials for diagnostic purposes.

Standard C

Technologists and Associated Personnel.

The number of radiologic and/or nuclear medical technologists and associated personnel employed, as well as their training and experience, is adequate for the workload, considering the complexities of the radiologic procedures and the amount of time necessary for their execution.

Factor 1. Technologists employed by the laboratory are certified by the American Registry of Radiologic Technologists, or registered by the Registry of Medical Technologists (ASCP) as nuclear medical technologists, or meet equivalent requirements.

Standard D

Interpretation of Procedures.

The laboratory provides for the interpretation of the results of each roentgenological and/or radioisotope procedure. This interpretation is made by a physician qualified in the field.

Factor 1. The interpretation of the results of each procedure is made only by a physician who is licensed to practice medicine in that State and has the appropriate specialized knowledge needed to arrive at the interpretation.

Standard E

Fluoroscopic Examinations.

Fluoroscopic examinations of patients are performed only by physicians whose training and experience are adequate to interpret the findings of the procedure.

Factor 1. Fluoroscopic procedures are not conducted by technologists.

Standard F

Report of Diagnostic Procedure.

A signed report is made by a physician qualified in the field for each diagnostic roentgenologic and/or isotope procedure, and is transmitted to the referring physician. Records are maintained of all such reports.

Factor 1. Records contain a concise statement of the referring physician's reason for requesting the procedure.

Factor 2. Copies of reports and radiographs are preserved or microfilmed in accordance with the State's statutes of limitations.

Standard G

Personnel Policies.

There are written personnel policies, prac-

tices, and procedures that adequately support sound laboratory practice.

Factor 1. Current employee records are maintained, and include a résumé of each employee's training and experience.

Factor 2. Files contain evidence of adequate health supervision of employees, such as results of pre-employment and periodic physical examinations, including chest x rays, and records of all illnesses and accidents occurring on duty.

Factor 3. Work assignments are consistent with qualifications.

Factor 4. There is a program for employee orientation.

Condition for Coverage

VIII. STANDARDS FOR SAFETY

THE LABORATORY MEETS PROFESSIONALLY APPROVED STANDARDS FOR SAFETY.

Standard A

Safety Program.

There is in effect a strict control program to reduce radiation and other hazards associated with the technical operations of the laboratory.

Factor 1. Proper safety precautions are maintained against fire and explosion hazards, electrical hazards, and radiation hazards.

Factor 2. Periodic inspections are made by local or State health authorities, or by other qualified individuals, and hazards so identified are promptly corrected. Records are maintained of such current inspections.

Factor 3. Personnel monitoring is used for those radiation workers whose exposures are likely to exceed 25 mR per week.

Factor 4. Radiation barriers and shielding are adequate to limit radiation exposures of personnel and the environs within acceptable limits.

Factor 5. Restriction of X-ray beam size is attained through proper and regular use of the appropriate limiting cone or the proper setting of the variable aperture collimator in radiographic procedures.

Factor 6. Appropriate filtration of the X-ray beam is used.

Factor 7. Only shockproof equipment is used.

Factor 8. All electrical equipment is grounded.

Factor 9. With fluoroscopes, attention is paid to modern safety design and good operating procedures; records are maintained of the exposure rate at the panel or table top of all fluoroscopes.

Factor 10. Radioactive materials are stored and used in accordance with the provisions of applicable Federal or State standards and conditions of licensure.

Factor 11. The space and equipment are adequate for the volume and diversity of procedures done by the laboratory.











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**HEALTH
INSURANCE
FOR THE AGED**

**CONDITIONS
FOR COVERAGE
OF SERVICES
OF INDEPENDENT
LABORATORIES**





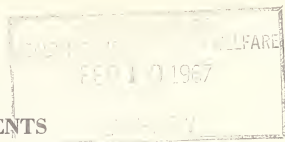


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U.S. Bureau of Health Insurance.



INTRODUCTION TO THE CONDITIONS FOR COVERAGE OF SERVICES OF INDEPENDENT LABORATORIES §405.1301

Introduction

The Conditions for Coverage of Services of Independent Laboratories and related policies set forth herein, which will be reflected in regulations of the Department of Health, Education, and Welfare, state the specific requirements that must be met by an independent laboratory in order for its services to qualify for reimbursement under the supplementary medical insurance part of the health insurance for the aged program. The services of a qualified independent laboratory for which reimbursement may be made under the supplementary medical insurance program relate only to diagnostic tests performed in a laboratory which is independent of a physician's office or a participating hospital. Diagnostic laboratory tests, for purposes of section 1861(s) (10) and (11) of the Social Security Act, do not include diagnostic X-ray tests.

Definition of Independent Laboratory

An independent laboratory performing diagnostic tests is one which is independent both of the attending or consulting physician's office and of a hospital which meets the conditions of participation in the program. "The laboratory a physician maintains for performing diagnostic tests in connection with his own practice would be exempt from . . . [the prescribed] standards but if the physician runs a laboratory which performs diagnostic work referred by other physicians the laboratory would be subject to these standards." (Report on H.R. 6675 of the Senate Committee on Finance, p. 43) Services furnished by out-of-hospital laboratories under the direction of a physician, such as a pathologist, are considered to be subject to the conditions where the physician holds himself and the facilities of his office out to other physicians as being available primarily for the performance of diagnostic tests. A laboratory maintained by a physician for performing diagnostic tests primarily for his own patients would be exempt from the conditions, even though such laboratory does diagnostic tests on referral from other physicians. Diagnostic tests furnished by out-of-hospital physicians, whose primary practice is directly attending patients and/or consultation, even though conducted partly through diagnostic procedures, are considered physician's services rather than clinical laboratory services. As such, the office in

which these services are provided is exempt from the conditions. Consultation is a deliberation of two or more physicians with respect to the diagnosis or treatment in any particular case. Consultation, as distinguished from providing clinical laboratory services, includes history taking, examination of the patient and, in each case, transmitting to the attending physician an opinion concerning diagnosis and/or treatment.

Section 1861(s) of the Social Security Act, which includes the provision for the coverage in the medical insurance program of diagnostic tests performed in an independent laboratory, provides that, as a condition for coverage of such tests, an independent laboratory, in any State in which State or local law provides for licensing laboratories, is licensed pursuant to such law or is approved by the agency of the State or locality responsible for such licensure as meeting the standards established for licensing. As a further condition, the statute requires that the independent laboratory meet such standards as the Secretary of Health, Education, and Welfare finds necessary to assure the health and safety of individuals with respect to whom these tests are performed.

The law makes provision for the designation of State health agencies, or other State agencies, to assist the Department in determining whether there is compliance with the conditions for coverage of services of independent laboratories. The designated State agencies will certify to the Department of Health, Education, and Welfare those laboratories which they find meet the conditions. Services provided in a laboratory that is determined to be in substantial compliance with the conditions relating to health and safety and which meet the statutory licensure requirement would be reimbursable under the medical insurance program.

Simultaneously with the release of these materials to interested individuals, organizations, and agencies, the Department is publishing conforming regulations in the Federal Register.

Conditions for Coverage of Services

In the preparation of the conditions for coverage of services, there has been extensive discussion and consultation with organizations and experts in the fields of radiology, clinical laboratory services, and medical

care. Groups consulted included, among others, representatives of State agencies, American Medical Association, College of American Pathologists, American College of Radiology, American Chemical Society, and American Association of Bioanalysts. The conditions have also been reviewed and concurred in by the Health Insurance Benefits Advisory Council, the statutory body established for the purpose of advising the Secretary on matters of general policy in the administration of this program and in the formulation of applicable regulations.

The conditions have been developed in accordance with the requirements, authorizations, and limitations of the law. The services of an independent laboratory will be reimbursable under the program only if the laboratory meets the statutory requirement of section 1861(s) (10) and there has been a determination by the Secretary of substantial compliance on the part of the laboratory with all the other conditions. These additional conditions (established in the interest of health and safety) are requirements which are essential to the maintenance of quality of care and the adequacy of the services and facilities which the laboratory provides. Variations in the type and size of laboratories and the nature and scope of services offered will be reflected in differences in the details of organization, staffing, and facilities. However, the test will be whether there is substantial compliance with each of the conditions.

Under the Health Insurance for the Aged Act, State agencies, operating under agreements with the Secretary, will be used by the Department in determining whether independent laboratories meet the conditions. Pursuant to this agreement, State agencies will certify to the Department findings as to whether independent laboratories are in substantial compliance with the conditions. Such certifications will include findings as to whether each of the conditions is substantially met. The Department, on the basis of such certification from the State agency, will determine whether or not the level of facilities and services of the laboratory represent the required achievement of substantial compliance with the conditions and will transmit to the laboratory a written notice of the determination.

Principles for the Evaluation of Independent Laboratories to Determine Whether They Are in Substantial Compliance with the Conditions

Independent laboratories will be considered in substantial compliance with the conditions upon acceptance by the Secretary of findings, adequately documented and certified to by the State agency, showing that:

- A. The laboratory meets the specific statutory requirement of section 1861(s) (10) and is found to be

operating in accordance with all the conditions with no significant deficiencies, or

- B. The laboratory meets the specific statutory requirement of section 1861(s) (10) but is found to have deficiencies with respect to one or more conditions, but

1. It is making reasonable plans and efforts to correct the deficiencies, and
2. Notwithstanding the deficiencies, it is rendering adequate service without hazard to the health and safety of individuals being served, taking into account special procedures or precautionary measures which have been or are being instituted.

Time Limitations on Certification of Substantial Compliance

All initial certifications by the State agency to the effect that an independent laboratory is in substantial compliance with the conditions will be for a period of 1 year, beginning with July 1, 1966, or, if later, with the date on which the laboratory is first found to be in substantial compliance with the conditions. State agencies may visit or resurvey laboratories where necessary to ascertain continued compliance or to accommodate to periodic or cyclical survey programs. A State may, at any time, find and certify to the Secretary that a laboratory is no longer in compliance.

If a laboratory is certified by the State agency and determined by the Secretary to be substantial compliance under the provisions of paragraph B., above, the following information will be incorporated into the finding and into the notice to the laboratory of the termination of the coverage of its services under the medical insurance program:

- A. A statement of the deficiencies which were found, and
- B. A description of progress which has been made and further action which is being taken to remove the deficiencies, and
- C. A scheduled time for a resurvey of the laboratory to be conducted not later than the ninth month (or earlier, depending on the nature of the deficiencies) of the period of certification.

Certification of Noncompliance

The State agency will certify that a laboratory is not in compliance with the conditions or, where a determination of compliance has been made, that a laboratory is no longer in compliance where:

- A. The laboratory is not in compliance with the statutory requirement of section 1861(s) (10), or
- B. The laboratory has deficiencies of such character as to seriously limit the capacity of the laboratory to render adequate service or to place health and

safety of individuals in jeopardy, and the State agency concludes after discussion with the laboratory that there is no early prospect of such significant improvement as to establish substantial compliance, or

- C. After a previous period or part thereof for which the laboratory was certified with a finding of significant deficiencies, there is a lack of progress toward a removal of deficiencies which the State agency finds are adverse to the health and safety of individuals being served.

Criteria for Determining Substantial Compliance

Findings made by a State agency as to whether an independent laboratory is in substantial compliance with the conditions require a thorough evaluation of the laboratory. The State evaluation will take into consideration:

- A. The degree to which each standard, as well as the total set of standards relating to a condition, is met:

- B. When there is a deficiency, whether the deficiency creates a serious hazard to health and safety; and
C. Whether the laboratory is making reasonable plans and efforts to correct the deficiency within a reasonable period.

Documentation of Findings

The findings of the State agency with respect to each of the conditions should be adequately documented. Where the State agency certifies to the Department of Health, Education, and Welfare that a laboratory is not in compliance with the conditions, such documentation should include a report of any discussions concerning the deficiencies, a report of the laboratory's responses with respect to such discussions, and the State agency's assessment of the prospects for such improvements as to enable the laboratory to achieve substantial compliance with the conditions.



CLINICAL LABORATORY
§405.1311

DEFINITION:

A clinical laboratory is a laboratory where microbiological, serological, chemical, hematological, biophysical, cytological, immunohematological, or pathological examinations are performed on materials derived from the human body, to provide information for the diagnosis, prevention or treatment of a disease of a medical condition.



Condition for Coverage

§405.1310

I. COMPLIANCE WITH STATE AND LOCAL LAWS
THE LABORATORY IS IN CONFORMITY WITH ALL APPLICABLE
STATE AND LOCAL LAWS.

Standard a

Licensure.

The laboratory, in any State in which State or applicable local law provides for the licensing of laboratories, (1) is licensed pursuant to such law, or (2) is approved, by the agency of the State or locality responsible for licensing laboratories, as meeting the standards established for such licensing.

Standard b

Licensed Staff.

The director and the staff of the laboratory are licensed or registered in accordance with applicable laws.

Standard c

Fire and Safety.

The laboratory is in conformity with laws relating to fire and safety, and to other relevant matters.



Condition for Coverage

§405.1312

II. LABORATORY DIRECTOR

THE CLINICAL LABORATORY IS UNDER THE DIRECTION OF A QUALIFIED PERSON.

Standard a

Administration.

The laboratory has a director who administers the technical and scientific operation of the laboratory including the reporting of findings of laboratory tests.

Factor 1. The director serves the laboratory full-time, or on a regular part-time basis. If he serves on a regular part-time basis, (a) he does not individually serve as director of more than three laboratories (hospital or independent) or, (b) he provides an associate, qualified under Standard b following, to serve as assistant director in each laboratory. Such assistant director does not serve more than three laboratories.

Factor 2. Commensurate with the laboratory work load, the director spends an adequate amount of time daily in the laboratory to direct and supervise the technical performance of the staff. An exception to the requirement for daily on-site direction may be made only in a rural area.

Factor 3. The director is responsible for the proper performance of all tests made in the laboratory.

Factor 4. The director is responsible for the employment of qualified laboratory personnel and their in-service training.

Factor 5. If the director is to be continuously absent for more than one month, arrangements are made for a qualified substitute director.

Standard b

Laboratory Director—Qualification.

The laboratory director meets one of the following requirements:

1. He is a physician certified in anatomical and/or clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology, or possesses qualifications which are equivalent to those required for such certification.
2. He is a physician who (a) is certified by the American Board of Pathology or the American Osteopathic Board of Pathology in at least one of the laboratory specialties, or (b) is certified by the American Board of Microbiology, the American Board of Clinical Chemistry, or other national accrediting board acceptable to the Secretary in

one of the laboratory specialties, or (c) subsequent to graduation has had four or more years of general laboratory training and experience, of which at least two were spent acquiring proficiency in one of the laboratory specialties in a clinical laboratory—with a director at the doctoral level—of a hospital, health department, university, or medical research institution, or in the case of a State which regulates clinical laboratory personnel, in a clinical laboratory acceptable to that State.

3. He holds an earned doctoral degree from an accredited institution¹ with a chemical, physical, or biological science as his major subject, and (a) is certified by the American Board of Microbiology, the American Board of Clinical Chemistry, or other national accrediting board acceptable to the Secretary in one of the laboratory specialties or, (b) subsequent to graduation, has had 4 or more years of general clinical laboratory training and experience, of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties in a clinical laboratory—with a director at the doctoral level—of a hospital, a health department, university, or medical research institution, or in the case of a State which regulates clinical laboratory personnel, in a clinical laboratory acceptable to that State.
4. For a period ending June 30, 1971, an exception to the requirements in paragraphs 1, 2, or 3 of this standard may be made if (a) the director was responsible for the direction of a clinical laboratory for 12 months within the five years preceding July 1, 1966; and (b) the State agency has evidence of successful participation of the laboratory which he directs in a State and/or State approved proficiency testing program covering all the specialties or subspecialties in which the laboratory performs tests (except that for a period ending July 31, 1967, in a State not yet having an approved proficiency testing program in operation, the State agency will give interim certification of compliance with respect to a clinical laboratory which otherwise meets the requirements, all approvals based on such interim certi-

¹“Accredited,” as used herein, refers to accreditation by a nationally recognized accrediting agency or association, as determined by the United States Commissioner of Education.

cation terminating no later than July 31, 1967); and (c) the director meets one of the following requirements:

- (a) the director holds a master's degree from an accredited institution with a chemical, physical, or biological science as his major subject and subsequent to graduation has had at least 4 years of pertinent clinical laboratory experience.
- (b) the director holds a bachelor's degree from an accredited institution with a chemical, physical, or biological science as his major subject and subsequent to graduation has had at least 6 years of pertinent clinical laboratory experience.

- (c) The director has achieved a satisfactory grade through an examination conducted by or under the sponsorship of the U.S. Public Health Service, provided that such examination shall no longer be conducted subsequent to July 1, 1970. For a period ending July 31, 1967, the State agency will give interim certification of compliance with respect to a clinical laboratory if such laboratory otherwise meets the requirements and if the director has indicated his intention in writing, to take the examination. All approvals based on such interim certifications shall terminate no later than July 31, 1967.

Condition for Coverage
§405.1313

III. SUPERVISION

THE CLINICAL LABORATORY IS SUPERVISED BY QUALIFIED
PERSONNEL.

Standard a

Supervision.

The laboratory has one or more supervisors who, under the general direction of the laboratory director, supervise technical personnel and reporting of findings, perform tests requiring special scientific skills, and, in the absence of the director, are held responsible for the proper performance of all laboratory procedures.

Factor 1. A laboratory director is considered to be qualified as a supervisor and, therefore, depending upon the size and functions of the laboratory, the laboratory director may also serve as the laboratory supervisor.

Factor 2. A qualified supervisor is on the premises during all hours in which tests are being performed.

Standard b

Supervisor—Qualification.

The laboratory supervisor meets one of the following requirements:

1. He (a) is a physician or has earned a doctoral degree from an accredited institution with a chemical, physical, or biological science as his major subject and (b) subsequent to graduation has had at least 2 years experience in one of the laboratory specialties in a clinical laboratory—with a director at the doctoral level—of a hospital, a health department, university, or medical research institution, or in the case of a State which regulates clinical laboratory personnel, in a clinical laboratory acceptable to that State.
2. He holds a degree of master of arts or master of science from an accredited institution with a major in one of the chemical, physical, or biological sciences and, subsequent to graduation, has had at least 4 years of pertinent laboratory experience of which not less than 2 years has been spent working in the designated laboratory specialty in a clinical laboratory—with a director at the doctoral level—of a hospital, a health department, university, or medical research institution, or in the case of a State which regulates clinical laboratory personnel, in a clinical laboratory acceptable to that State.
3. He holds a degree of bachelor of arts or bachelor of science from an accredited institution with a

major in one of the chemical, physical, or biological sciences and, subsequent to graduation (a) has had at least 6 years of pertinent laboratory experience of which not less than 2 years has been spent working in the designated laboratory specialty in a clinical laboratory—with a director at the doctoral level—of a hospital, a health department, university, or medical research institution, or in the case of a State which regulates clinical laboratory personnel, in a clinical laboratory acceptable to that State; and (b) has successfully completed pertinent courses which, when combined with the foregoing experience, will provide technical and professional knowledge comparable to that of 2 above.

4. He is qualified as a clinical laboratory technologist pursuant to the provisions of Condition V, Standard b 1, 2, 3, or 4, and (a) has had at least 6 years of pertinent laboratory experience of which not less than 2 years has been spent working in the designated laboratory specialty in a clinical laboratory—with a director at the doctoral level—of a hospital, university, health department, or medical research institution or in the case of a State which regulates clinical laboratory personnel, in a clinical laboratory acceptable to that State; and (b) has successfully completed pertinent courses which, when combined with the foregoing experience, will provide a technical and professional knowledge comparable to that of 2 above.
5. For a period ending June 30, 1971, an exception to the requirements in paragraphs 1, 2, 3, or 4 of this Standard, may be made if (a) the supervisor was performing the duties of a clinical laboratory supervisor on, or within the 5 years preceding July 1, 1966, and (b) the supervisor has had at least 15 years of pertinent clinical laboratory experience prior to July 1, 1966, provided that a minimum of 30 semester hours of credit toward a bachelor's degree with a chemical, physical, or biological science as his major subject or 30 semester hours in an approved school of medical technology shall reduce the required years of experience by 2 years, with any additional hours further reducing the required years of experience at the rate of 15 hours for one year.



Condition for Coverage

§405.1314

IV. TESTS PERFORMED

THE CLINICAL LABORATORY PERFORMS ONLY THOSE LABORATORY TESTS AND PROCEDURES THAT ARE WITHIN THE SPECIALTIES IN WHICH THE LABORATORY DIRECTOR, SUPERVISORS, OR PERSONS ENGAGED TO PERFORM THE TESTS ARE QUALIFIED.

Standard a

Proficiency Testing.

To the extent that a State health department, directly or through a local health department, makes on-going proficiency testing services in one or more laboratory specialties available to all or to a class of laboratories, the laboratory participates in the program in those specialties in which the laboratory performs tests; and the laboratory does not perform tests in those specialties in which the State or local health department reports an unfavorable evaluation.

Standard b

Procedures and Tests—Competency.

The laboratory performs only those laboratory procedures and tests that are within the specialties or subspecialties in which the laboratory director, supervisors, or persons engaged to perform the tests are qualified.

Factor 1. If the laboratory director or supervisor is a pathologist certified in both anatomical and clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possesses qualifications which are equivalent to those required for certification, the laboratory may perform laboratory procedures and tests in all specialties.

Factor 2. If neither the director nor supervisor has the qualifications described in Factor 1, and the laboratory performs tests in the specialty of microbiology, including the subspecialties of bacteriology, serology, virology, mycology and parasitology, the laboratory engages the services of a qualified director or supervisor, as defined previously, who (a) holds an earned doctoral or master's degree in microbiology from an accredited institution, or is a physician and (b) subsequent to graduation has had at least 4 years' experience in clinical microbiology.

Factor 3. If Factor 1 is not met and the laboratory performs tests in the specialty of immunohematology, including the subspecialties of blood groupings and RH typing, it engages the services of a qualified director or supervisor, as defined previously, who is a physician with at least 2 years' experience in clinical hematology subsequent to graduation.

Factor 4. If Factor 1 is not met and the laboratory performs tests in the specialty of hematology, includ-

ing gross and microscopic examination of the blood, it engages the services of a qualified director or supervisor, as defined previously, who holds a master's or bachelor's degree in biology, immunology, or microbiology from an accredited institution and subsequent to graduation has had at least 4 years' experience in hematology.

Factor 5. If Factor 1 is not met and the laboratory performs tests in the specialty of clinical chemistry, it engages the services of a qualified director or supervisor, as defined previously, who (a) holds an earned doctoral or master's degree in chemistry or biochemistry from an accredited institution or is a physician, and (b) subsequent to graduation has had at least 4 years' experience in clinical chemistry.

Factor 6. If Factor 1 is not met and the laboratory performs tests in the specialty of tissue pathology then it engages the services of a pathologist who is certified in anatomical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology or possesses qualifications which are equivalent to those required for certification.

Factor 7. If Factor 1 is not met and the laboratory performs tests in the specialty of exfoliative cytology, it engages the services of a physician who: (a) is certified by the American Board of Pathology or the American Osteopathic Board of Pathology, or possesses qualifications which are equivalent to those required for certification or (b) is certified by the American Society of Cytology to practice cytopathology.

Factor 8. The laboratory whose director qualifies under Condition II, Standard b4, may perform tests in the laboratory specialties (a) in which such director is qualified by training and experience, or in which he has achieved a satisfactory grade through an examination conducted by or under the sponsorship of the U.S. Public Health Service (see Condition II, Standard b4(c)), and (b) in which successful participation in a State or State approved proficiency testing program has been demonstrated. It performs tests in other laboratory specialties only if the supervisor meets the appropriate requirements of 1 to 7 above. The laboratory may not, on the basis of the director's qualifications under Condition II, Standard b4, perform tests requiring the services of a physician, namely, tissue pathology, cytology, and immunohematology.



Condition for Coverage

§405.1315

V. TECHNICAL PERSONNEL

THE CLINICAL LABORATORY HAS A SUFFICIENT NUMBER OF PROPERLY QUALIFIED TECHNICAL PERSONNEL FOR THE VOLUME AND DIVERSITY OF TESTS PERFORMED.

Standard a

Technologist—Duties.

The laboratory employs a sufficient number of clinical laboratory technologists to proficiently perform under general supervision the clinical laboratory tests which require the exercise of independent judgment.

Factor 1. The clinical laboratory technologists perform tests which require the exercise of independent judgment and responsibility, with minimal supervision by the director or supervisors, in only those specialties or subspecialties in which they are qualified by education, training, and experience.

Factor 2. With respect to specialties in which the clinical laboratory technologist is not qualified by education, training, or experience, he functions only under direct supervision and performs only tests which require limited technical skill and responsibility.

Factor 3. Clinical laboratory technologists are in sufficient number to adequately supervise the work of technicians and trainees.

Standard b

Technologist—Qualifications.

Each clinical laboratory technologist possesses a current license as a clinical laboratory technologist issued by the State, if such licensing exists, and meets one of the following requirements:

1. Successful completion of a full course of study which meets all academic requirements for a bachelor's degree in medical technology from an accredited college or university.
2. Successful completion of 3 academic years of study (a minimum of 90 semester hours or equivalent) in an accredited college or university which met the specific requirements for entrance into, and the successful completion of a course of training of at least 12 months in a school of medical technology approved by the Council on Medical Education and Hospitals of the American Medical Association.
3. Successful completion in an accredited college or university of a course of study which meets all academic requirements for a bachelor's degree in one of the chemical, physical, or biological sci-

ences, and additional experience and/or training covering several fields of medical laboratory work, provided the combination has given the applicant the equivalent of the education and training in medical technology described in paragraphs 1 or 2 above.

4. Successful completion of 3 years (90 semester hours or equivalent) in an accredited college or university with a distribution of courses as shown below, and, in addition, successful experience and/or training covering several fields of medical laboratory work of such length (not less than 1 year), and of such quality that this experience or training, when combined with the education, will have provided the applicant with education and training in medical technology equivalent to that described in paragraphs 1 or 2 of this standard. Distribution of course work: (Where semester hours are stated, it is understood that the equivalent in quarter hours is equally acceptable. The specified courses must have included lecture and laboratory work. Survey courses are not acceptable.) (a) For those whose training was completed prior to September 15, 1963: At least 24 semester hours in chemistry and biology courses of which not less than 9 semester hours must have been in chemistry and must have included at least 6 semester hours in inorganic chemistry, and not less than 12 semester hours must have been in biology courses pertinent to the medical sciences. (b) For those whose training was completed after September 15, 1963: Sixteen semester hours in chemistry courses which included at least 6 semester hours in inorganic chemistry and are acceptable toward a major in chemistry; 16 semester hours in biology courses which are pertinent to the medical sciences and are acceptable toward a major in the biological sciences; and 3 semester hours of mathematics.
5. For a period ending June 30, 1971, an exception to the requirements in paragraphs 1, 2, 3, or 4 of this standard may be made if (a) the technologist was performing the duties of a clinical laboratory technologist on, or within the 5 years preceding, July 1, 1966, and (b) the technologist has had at least 10 years of pertinent clinical laboratory experience prior to July 1,

1966, provided that a minimum of 30 semester hours of credit toward a bachelor's degree from an accredited institution with a chemical, physical or a biological science as his major subject or 30 semester hours in an approved school of medical technology shall reduce the required years of experience by 2 years, with any additional hours further reducing the required years of experience at the rate of 15 hours for one year.

Standard c

Technician—Duties.

Clinical laboratory technicians are employed in sufficient number to meet the workload demands of the laboratory and they function only under direct supervision of a clinical laboratory technologist.

Factor 1. Each clinical laboratory technician performs only those laboratory procedures which require limited technical skill and responsibility and a minimal exercise of independent judgment.

Factor 2. No one with lesser qualifications than a clinical laboratory technician performs laboratory procedures, although manual and clerical supplemental services may be rendered by others.

Factor 3. No clinical laboratory technician performs tests in the absence of a clinical laboratory technologist.

Standard d

Technician—Qualifications.

Each clinical laboratory technician possesses a current license as a clinical laboratory technician issued by the State, if such licensing exists, and meets one of the following requirements:

1. He is a high school graduate and subsequent to graduation has completed at least 1 year in a technician training program approved by the Council on Medical Education and Hospitals of the American Medical Association or approved by the Secretary.
2. He is a high school graduate and subsequent to graduation has served 2 years as a technician trainee in a clinical laboratory with a director at the doctoral level, or in the case of a State which regulates clinical laboratory personnel, in a clinical laboratory acceptable to that State.
3. He is a high school graduate and subsequent to graduation has successfully completed an official military medical laboratory procedures course of

at least 50 weeks' duration, and has held, at the journeyman's level, the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician).

4. For a period ending June 30, 1971, an exception to the requirements in paragraphs 1, 2, or 3 of this standard may be made if (a) the technician was performing the duties of clinical laboratory technician on, or within the five years preceding, July 1, 1966, and (b) the technician has had at least 5 years of pertinent clinical laboratory experience prior to July 1, 1966, provided that a minimum of 30 semester hours of credit toward a bachelor's degree from an accredited institution with a chemical, physical, or biological science as his major subject, shall reduce the required years of experience by 2 years, with any additional hours further reducing the required years of experience at the rate of 15 hours for one year; and provided also that the required 5 years of experience shall not be so reduced by more than 4 years.

Standard e

Collection of Specimens.

No person other than a licensed physician or one otherwise authorized by law manipulates a patient for the collection of specimens, except that qualified technical personnel of the laboratory may collect blood or remove stomach contents and collect material for smears and culture under the direction, or upon the written request, of a licensed physician.

Standard f

Personnel policies.

There are written personnel policies, practices, and procedures that adequately support sound laboratory practice.

Factor 1. Current employee records are maintained and include a resume of each employee's training and experience.

Factor 2. Files contain evidence of adequate health supervision of employees, such as results of pre-employment and periodic physical examinations, including chest X-rays, and records of all illnesses and accidents occurring on duty.

Factor 3. Work assignments are consistent with qualifications.

Factor 4. There is a program for employee orientation.

VI. RECORDS, EQUIPMENT AND FACILITIES

THE CLINICAL LABORATORY MAINTAINS RECORDS, EQUIPMENT, AND FACILITIES WHICH ARE ADEQUATE AND APPROPRIATE FOR THE SERVICES OFFERED.

Standard A

Laboratory Management.

Space, facilities, and equipment are adequate to properly perform the services offered by the laboratory.

Factor 1. There is an adequate quality control program in effect including the use, where applicable, of reference or control sera and other biological samples, concurrent calibrating standards, and control charts recording standard readings.

Factor 2. All equipment is in good working order, routinely checked, and precisely calibrated.

Factor 3. Work bench space is ample, well-lighted, and convenient to sink, water, gas, suction, and electrical outlets as necessary.

Factor 4. The laboratory is properly ventilated.

Factor 5. Notebooks of appropriate current laboratory methods are available.

Factor 6. Adequate fire precautions are observed.

Factor 7. There is freedom from unnecessary physical, chemical, and biological hazards.

Standard B

Sterilization.

Syringes, needles, lancets, or other blood letting devices capable of transmitting infection from one person to another are not reused unless they are sterilized prior to each use, after first having been wrapped or covered in a manner which will insure that they remain sterile until the next use.

Factor 1. Each sterilizing cycle contains an indicator device which assures proper sterilization.

Standard C

Examination and Reports.

The laboratory examines specimens only at the request of a licensed physician, dentist, or other person authorized by law to use the find-

ings of laboratory examinations and reports only to those authorized by law to receive such results.

Factor 1. If the patient is sent to the laboratory, a written request for the desired laboratory procedures is obtained from a person authorized by law to use findings of laboratory examinations.

Factor 2. If only a specimen is sent, it is accompanied by a written request.

Factor 3. If the laboratory receives reference specimens from another laboratory it reports back to the laboratory submitting the specimens.

Standard D

Specimens—Records.

The laboratory maintains a record indicating the daily accession of specimens each of which is numbered or otherwise appropriately identified.

Factor 1. Records contain the following information:

- (a) The laboratory number or other identification of the specimen.
- (b) The name and other identification of the person from whom the specimen was taken.
- (c) The name of the licensed physician or other authorized person or clinical laboratory who submitted the specimen.
- (d) The date the specimen was collected by the physician or other authorized person.
- (e) The date the specimen was received in the laboratory.
- (f) The condition of unsatisfactory specimens when received (e.g., broken, leaked, hemolyzed or turbid, etc.).
- (g) The type of test performed.
- (h) The result of the laboratory test or cross reference to results and the date of reporting.

Standard E

Laboratory Report and Record.

The laboratory report is sent promptly to the licensed physician or other authorized person who requested the test and a suitable record of each test result is preserved by the laboratory in accordance with the State's statutes of limitations.

Factor 1. The laboratory director is responsible for the laboratory report.

Factor 2. Duplicate copies or a suitable record of laboratory reports are filed in the laboratory in a manner which permits ready identification and accessibility.

Factor 3. Tissue pathology reports utilize acceptable terminology of a recognized system of disease nomenclature.

Factor 4. The results of laboratory tests or procedures or transcript thereof are not sent to the patient concerned except with the written consent of the physician or other authorized person who requested the test.





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**HEALTH
INSURANCE
FOR THE AGED**

**PRINCIPLES OF
REIMBURSEMENT
FOR PROVIDER
COSTS**

U.S. Bureau of Health Insurance



U.S. DEPARTMENT OF
HEALTH, EDUCATION, AND WELFARE
SOCIAL SECURITY ADMINISTRATION

HIM-5 (5-66)

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PRINCIPLES OF REIMBURSEMENT FOR PROVIDER COSTS UNDER TITLE XVIII OF THE SOCIAL SECURITY ACT AS AMENDED (PUBLIC LAW 89-97)

Introduction

Under the health insurance program for the aged, the amount paid to any provider of services—i.e., hospital, extended care facility, or home health agency—for the covered services furnished to beneficiaries is required by section 1814(b) of the Social Security Act to be the “reasonable cost” of such services. In connection with the definition of this term, section 1861(v) provides that such costs shall be determined in accordance with regulations establishing the method or methods to be used, and the items to be included in determining costs for various types or classes of institutions, agencies, and services.

These principles of reimbursement and the related policies described herein establish the guidelines and procedures to be used by institutional providers, fiscal intermediaries, and the Social Security Administration in determining reasonable cost. They represent the policies which will be incorporated into regulations of the Department of Health, Education, and Welfare for purposes of governing payments under the health insurance program.

The principles of reimbursement will be applied locally on behalf of the program by Blue Cross and certain private insurance companies acting as fiscal intermediaries in the payment of claims. These voluntary insurance organizations were selected after nomination by groups or associations of hospitals. Extended care facilities and home health agencies may similarly nominate such intermediaries. The fiscal intermediaries will be responsible for paying the bills of program beneficiaries for covered services received in participating hospitals and other institutions under the medicare program. A provider may deal directly with the Social Security Administration, in which case the same principles will be used in making payment for services.

In consideration of the wide variations in size and scope of services of providers and regional differences that exist, the principles are flexible on many points. They offer certain alternatives and options designed to fit individual circumstances and to allow time for those providers who do not already collect the statistical and financial data necessary for the reporting of costs to develop the necessary records.

An important role of the fiscal intermediary, in addition to claims processing and payment, and other

assigned responsibilities, is to furnish consultative services to providers in the development of accounting and cost-finding procedures which will assure them equitable payment under the program.

The American Hospital Association is prepared to give guidance and assistance to hospital providers through its hospital administrative services and its cost allocation program. Providers may also look to their State and metropolitan associations, to local chapters of the American Association of Hospital Accountants, and to their own public accountants for assistance.

Development of the Principles

Congress indicated its intent that in the framing of regulations for the determination of reasonable cost, consideration should be given to the principles generally applied by national organizations and established prepayment programs. Accordingly, in the development of the principles of reimbursement there has been extensive consultation with representatives of the American Hospital Association and with many others including representatives of the American Nursing Home Association, the American Association of Hospital Accountants, the National Blue Cross Association, individual Blue Cross plans, the Health Insurance Association of America, and the private insurance field as well as State and Federal agencies which purchase hospital and institutional services. There have been meetings also with hospital administrators and comptrollers, nationally recognized authorities in the field of health care costs, and many other interested individuals and organizations. The Health Insurance Benefits Advisory Council, a 16-member non-Federal body established for the purpose of providing advice in the formulation of regulations, has given prolonged attention to the subject of cost reimbursement, and these principles are based on their advice and have their support.

In developing the principles of reimbursement, the Social Security Administration and the others who have participated were mindful of certain weaknesses that have existed in some other third-party reimbursement arrangements in the past. They were mindful, too, of new goals in providing reimbursement, and of the statutory requirements and the legislative history of the medicare program. Putting these several points together, certain tests were evolved for the principles of reimbursement and certain goals were established that they should be designed to accomplish.

In general terms, these are the tests or objectives:

1. That the methods of reimbursement should result in current payment so that institutions will not be disadvantaged, as they sometimes are under other arrangements, by having to put up money for the purchase of goods and services well before they receive reimbursement.
2. That, in addition to current payment, there should be retroactive adjustment so that increases in costs are taken fully into account as they actually occurred, not just prospectively.
3. That there be a division of the allowable costs between the beneficiaries of this program and the other patients of the hospital that takes account of the actual use of services by the beneficiaries of this program and that is fair to each provider individually.
4. That there be sufficient flexibility in the methods of reimbursement to be used, particularly at the beginning of the program, to take account of the great differences in the present state of development of recordkeeping.
5. That the principles should result in the equitable treatment of both nonprofit organizations and profitmaking organizations.
6. That there should be a recognition of the need of hospitals and other providers to keep pace with growing needs and to make improvements.

The Approach to Cost Reimbursement

In formulating methods for making fair and equitable reimbursement for services rendered beneficiaries of the program, pursuant to the intent of the law, payment is to be made on the basis of current costs of the individual provider, rather than costs of a past period or a fixed negotiated rate. All necessary and proper expenses of an institution in the production of services, including normal standby costs, are recognized. Furthermore, pursuant to the law and the reports of the Committee on Ways and Means of the House of Representatives and the Committee on Finance of the United States Senate, the share of the total institutional cost that is borne by the program is related to the care furnished beneficiaries so that no part of their cost would need to be borne by other patients. Conversely, costs attributable to other patients of the institution are not to be borne by the program. Thus, the application of this approach, with appropriate accounting support, will result in meeting actual costs of services to beneficiaries as they vary from institution to institution.

In complying with congressional intent that full advantage be taken of the experience of national organizations in applying principles of reimbursement, an important guideline has been the American Hospital Association's "Principles of Payment for Hospital Care."

One of the basic concepts in the American Hospital Association statement is found in its principle 1.100 which states, "Agencies purchasing hospital services should pay the cost incurred in providing services for which they are responsible under their agreements with hospitals."

A basic concern of providers has been the items to be included in reimbursable costs. These have been thoroughly documented by the organizations and individuals conferring with the Social Security Administration and have been given every consideration in the development of these principles. As formulated herein, the principles give recognition to such factors as depreciation, interest, bad debts, educational costs, compensation of owners, and allowance for capital funds to secure, preserve, and improve service-rendering capabilities and in lieu of a direct return on equity capital.

With respect to allowable costs some items of inclusion and exclusion are:

- An appropriate part of the net cost of approved educational activities will be included.
- Costs incurred for research purposes, over and above usual patient care, will not be included.
- Grants, gifts, and income from endowments will not be deducted from operating costs unless they are designated by the donor for the payment of specific operating costs.
- The value of voluntary services provided by sisters or other members of religious orders is includable in the amount that would be paid others for similar work.
- Discounts and allowances received on the purchase of goods or services are reductions of the cost to which they relate.
- Bad debts growing out of the failure of a beneficiary to pay the deductible, or the coinsurance, will be reimbursed (after bona fide efforts at collection).
- Charity and courtesy allowances are not includable, although "fringe benefit" allowances for employees under a formal plan will be includable as part of their compensation.
- A reasonable allowance of compensation for the services of owners in profitmaking organizations will be allowed providing their services are actually performed in a necessary function.

Of major concern to providers has been the factor of depreciation. In developing these principles of reimbursement for the health insurance program, all of the considerations inherent in allowances for depreciation were studied. The principles, as presented, provide options to meet varied situations. Depreciation will essentially be on an historical cost basis but since many institutions do not have adequate records of old

assets, the principles provide an optional allowance in lieu of such depreciation for assets acquired before 1966. For assets acquired after 1965, the historical cost basis must be used. All assets actually in use for production of services for medicare beneficiaries will be recognized even though they may have been fully or partially depreciated for other purposes. Assets financed with public funds may be depreciated. In general, the options for accelerated depreciation allowed by the income tax laws will be permitted. Although funding of depreciation is not required, there is an incentive for it since income from funded depreciation is not considered as an offset which must be taken to reduce the interest expense that is allowable as a program cost.

An allowance is provided in recognition of the continuing need for capital funds to secure, preserve, and improve service-rendering capability. In part this allowance is in lieu of a direct return on net capital investment and in part is a recognition of various uncertainties that are inherent in the application of any cost formula at this stage of cost-finding capabilities. The allowance will apply to both nonprofit and profit-making organizations alike. This avoids the anomalous result that would arise from reimbursing a profitmaking organization more than a nonprofit organization for rendering exactly the same service solely by reason of allowing a return on investment in one case but not the other. The allowance will be computed by taking 2 percent of total allowable cost (for purposes of determining this base, interest expense will be subtracted). The amount computed will be subject to the limitation that the total allowance not exceed a reasonable long-term interest rate on net capital investment.

The Program's Share of Allowable Costs

Consistent with prevailing practice where third-party organizations pay for health care on a cost basis, reimbursement under the health insurance program will involve determination of (1) each provider's allowable costs for producing services, and (2) the share of these costs which is to be borne by the program. The provider's costs are to be determined in accordance with the principles reviewed in the preceding discussion relating to allowable costs; the share to be borne by the program is to be determined in accordance with principles relating to apportionment of cost.

The Social Security Administration has made an intensive study of the various methods of apportioning costs which are in current usage and has given careful consideration to factors which should determine the program's share of a provider's allowable costs. In the study and consideration devoted to this matter, the objective has been to adopt methods for use under the program that would, to the extent reasonably possible, result in the program's share of a provider's total al-

lowable costs being the same as the program's share of the provider's total services. This result is essential for carrying out the statutory directive that the program's payments to providers should be such that the costs of covered services for beneficiaries would not be passed on to nonbeneficiaries, nor would the cost of services for nonbeneficiaries be borne by the program.

A basic factor bearing upon apportionment of costs is that program beneficiaries are not a cross section of the total population. Nor will they constitute a cross section of all patients receiving services from most of the providers that participate in the program. Available evidence shows that the use of services by persons age 65 and over differs significantly from other groups. Consequently, the objective sought in the determination of the program's share of a provider's total costs means that the methods used for apportionment must take into account the differences in the amount of services received by patients who are beneficiaries and other patients served by the provider.

The method most widely used at the present time by third-party purchasers of inpatient hospital care apportions a provider's total costs among groups served on the basis of the relative number of days of care used. This method, commonly referred to as average per diem cost, does not take into account variations in the amount of service which a day of care may represent and thereby assumes that the patients for whom payment is made on this basis are average in their use of service. In advocating this method, it is significant that the American Hospital Association in Principles of Payment for Hospital Care comments as follows: "An average per diem cost, computed under a reimbursable cost formula, should be used to establish a rate of payment under contractual agreements with third-party agencies when the patients for whom a contracting agency is responsible are average for the hospital concerned."

In considering the average per diem method of apportioning cost for use under the program, the difficulty encountered is that the preponderance of presently available evidence strongly indicates that the over-65 patient is not typical from the standpoint of average per diem cost. On the average he stays in the hospital twice as long and therefore the ancillary services that he uses are average¹ over the longer period of time, resulting in an average per diem cost for the aged alone, significantly below the average per diem for all patients.

Moreover, the relative use of services by aged patients as compared to other patients differs significantly among institutions. Consequently, considerations of equity among institutions are involved as well as that of effectiveness of the apportionment method under the

program in accomplishing the objective of paying each provider fully, but only, for services to beneficiaries.

A further consideration of long-range importance is that the relative use of services by aged and other patients can be expected to change, possibly to a significant extent in future years. The ability of apportionment methods used under the program to reflect such change is an element of flexibility which has been regarded as important in the formulation of the cost reimbursement principles.

An alternative to the relative number of days of care as a basis for apportioning costs is the relative amount of charges billed by the provider for services to patients. The amount of charges is the basis upon which the cost of hospital care is distributed among patients who pay directly for the services they receive. Payment for services on the basis of charges applies generally under insurance programs where individuals are indemnified for incurred expense, a form of health insurance widely held throughout the Nation. Also, charges to patients are commonly a factor in determining the amount of payment to hospitals under insurance programs providing service benefits, many of which pay "costs or charges, whichever is less" and some of which pay exclusively on the basis of charges. In all of these instances, the provider's own charge structure and method of itemizing services for the purpose of assessing charges is utilized as a measure of the amount of services received and as the basis for allocating responsibility for payment among those receiving the provider's services.

In this connection, it is pertinent that the Principles of Payment for Hospital Care, endorsed by the American Hospital Association, state that, "Established charges to self-paying patients for similar services and accommodations should be based upon and be reasonably related to the cost." (Principle 1.203) As charges are related more closely to cost through the application of this principle by institutions, the factor of charges becomes increasingly indicative of the relative amount of services received by patients in various classifications.

An increasing number of third-party purchasers who pay for services on the basis of cost are developing methods which utilize charges to measure the amount of services for which they have responsibility for payment. In this approach, the amount of charges for such services as a proportion of the provider's total charges to all patients is used to determine the proportion of the provider's total costs for which the third-party purchaser assumes responsibility. The approach is subject to numerous variations. It can be applied to the total of charges for all services combined or it can be applied to components of the provider's activities for which the amount of costs and charges are ascertained

through a breakdown of data from provider's accounting records.

For the application of the approach to components, which represent types of services, the breakdown of total costs is accomplished by "cost-finding" techniques under which indirect costs and nonrevenue activities are allocated to revenue-producing components for which charges are made as services are rendered. These cost-finding techniques are the same as those which have long been advocated by the American Hospital Association and others as a management tool for the evaluation and improvement of operational efficiency in patient care institutions.

Methods of Apportionment Under the Program

The principles for reimbursement under the program establish two basic methods, either of which may be used at the option of a provider, for the determination of the share of allowable costs for which payment is to be made to the provider.

The first alternative is to apply the beneficiaries' share of total charges, on a departmental basis, to total costs for the respective departments. Use of this department-by-department method will involve determination, by cost-finding methods, of the total costs for each of the institution's departments that are revenue-producing, i.e., departments providing services to patients for which charges are made.

The second alternative is a combination method. Under this method, as applied to inpatient care, that part of a provider's total allowable cost which is attributable to routine services (room, board, nursing service) is to be apportioned on the basis of the relative number of patient days for beneficiaries and for other patients, i.e., an average cost per diem basis. The residual part of the provider's allowable cost, attributable to nonroutine or ancillary services, is to be apportioned on the basis of the beneficiaries' share of the total charges to patients by the provider for nonroutine or ancillary services. The amounts computed to be the program's share of the two parts of the provider's allowable costs are then combined in determining the amount of reimbursement under the program. Use of the combined method will necessitate cost finding to determine the division of the provider's total allowable costs into the two parts, although it would be less involved than for the first alternative, the department-by-department method.

It is recognized that many hospitals and other providers do not currently employ methods for ascertaining the cost of the services they produce, either by departmental or other groupings of services. Although the use of cost finding has become more extensive among institutions in recent years, for a large number of providers use of the apportionment methods under the pro-

gram will involve compiling information needed as a basis for breaking down total costs into departmental costs or between routine services and other services, as would need to be done at the end of each accounting year.

To avoid an undue burden on providers and to allow ample time for all providers to adopt the cost-finding methods needed for the apportionment methods under the program, a temporary method may be used, at the option of the provider, for accounting periods ending before January 1, 1968. Under this option, a provider may employ the combination method of apportionment by using an estimated percentage obtained from the intermediary as the basis for arriving at a division of total allowable costs between routine and other services. This estimated percentage basis for division of costs will be accepted in lieu of actual cost finding as the basis for the division in the initial reporting period(s) of any provider of service. Furthermore, where there are special factors which make the apportionment methods difficult to apply, the intermediary may approve appropriate adaptations to accomplish the objective of determining the share of the provider's allowable costs which is attributable to services rendered to beneficiaries.

Payments to Providers

At the beginning of the program, the fiscal intermediaries will establish a basis for interim payment to each provider. This may be done by one of several methods. Where an intermediary is already paying the provider on a cost basis, the intermediary can adjust its rate of payment to an estimate of the result under the program's principles of reimbursement. Where no organization is paying the provider on a cost basis, the intermediary can obtain the previous year's financial statement from the provider and, by applying the principles of reimbursement, compute or approximate an appropriate rate of payment. The interim payment may be related to last year's average per diem, or to charges, or to any other ready basis of approximating costs.

At the end of the period, the actual apportionment, based on the cost finding and apportionment methods

selected by the provider, will determine the program's reimbursement for the actual services provided to beneficiaries during the period.

Basically, therefore, interim payments to providers will be made for services throughout the year, with final settlement on a retroactive basis at the end of the accounting period. Interim payments will be made as often as possible and in no event less frequently than once a month. The retroactive payments will take fully into account the costs that were actually incurred and settle on an actual, rather than on an estimated basis.

In addition to the basic procedure for payment to a provider following the submission of bills to the intermediary, payment will be made upon request by the provider on a basis designed to reimburse concurrently as services are furnished to beneficiaries. The amount of such payment will be computed by the intermediary initially on an estimated basis and periodically adjusted to represent the average level of services unreimbursed by the basic payment procedure.

Financial Data and Reports

The principles of cost reimbursement will require that providers maintain sufficient financial records and statistical data for proper determination of costs payable under the program. The program will follow standardized definitions, accounting, statistics, and reporting practices which are widely accepted in the hospital and related fields. Changes in these practices and systems will not be required in order to determine costs payable under the principles of reimbursement. Essentially, the methods of determining costs payable under the program involve making use of data available from the institution's basic accounts, as usually maintained, to arrive at equitable and proper payment for services to beneficiaries.

Cost reports will be required from providers on an annual basis with reporting periods based on the provider's accounting year. In the interpretation and application of the principles of reimbursement, the fiscal intermediaries will be an important source of consultative assistance to providers and will be available to deal with questions and problems on a day-to-day basis.



PRINCIPLES FOR SPECIFIC REIMBURSABLE COSTS

1-1 Depreciation

1-1A Allowance for Depreciation Based on Asset Costs

Principle

An appropriate allowance for depreciation on buildings and equipment is an allowable cost. The depreciation must be: (1) identifiable and recorded in the provider's accounting records; (2) based on the historical cost of the asset or fair market value at the time of donation in the case of donated assets; and (3) prorated over the estimated useful life of the asset using the straight-line method or accelerated depreciation under the declining balance or sum-of-the-years' digits methods.

Definitions

Historical cost is the cost incurred by the present owner in acquiring the asset.

Fair market value is the price that the asset would bring by bona fide bargaining between well-informed buyers and sellers at the date of acquisition. Usually the fair market price will be the price at which bona fide sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition.

Under the straight-line method of depreciation, the cost or other basis (e.g., donated) of the asset, less its estimated salvage value, if any, is determined first. Then this amount is distributed in equal amounts over the period of the estimated useful life of the asset.

Under the declining balance method, the annual depreciation allowance is computed by multiplying the undepreciated balance of the asset each year by a uniform rate up to double the straight-line rate.

Under the sum-of-the-years' digits method, the annual depreciation allowance is computed by multiplying the depreciable cost basis (cost less salvage value) by a constantly decreasing fraction. The numerator of the fraction is represented by the remaining years of useful life of the asset at the beginning of each year, and the denominator is always represented by the sum of the years of useful life at the time of acquisition.

Comments

Although funding of depreciation is not required, it is strongly recommended that providers use this mechanism as a means of conserving funds for replacement of depreciable assets, and coordinate their planning of capital expenditures with areawide planning activities of community and State agencies. As an incentive for funding, investment income on funded depreciation will not be treated as a reduction of allowable interest expense.

Appropriate recording of depreciation encompasses the identification of the depreciable assets in use, the assets' historical costs, the method of depreciation, estimated useful life, and the assets' accumulated depreciation. The Chart of Accounts published by the American Hospital Association and publications of the Internal Revenue Service are to be used as guides for the estimation of the useful life of assets.

Proration of the cost of an asset over its useful life will be allowed on the straight-line, the declining balance, or the sum-of-the-years' digits methods. The provider may choose to use one of the methods on a single asset or group of assets and another method on others. In applying the declining balance or sum-of-the-years' digits method to an asset that is not new, the undepreciated balance of the asset is to be treated as the cost of a new asset in computing the depreciation.

A provider may change from the straight-line method to an accelerated method or vice versa upon advance approval from the intermediary on a prospective basis with the request being made before the end of the first month of the prospective reporting period. Only one such change with respect to a particular asset may be made by a provider.

Gains and losses realized from the disposal of depreciable assets are to be included in the determination of allowable cost. The extent to which such gains and losses are includable is to be calculated on a proration basis recognizing the amount of depreciation charged under the program in relation to the amount of depreciation, if any, charged or assumed in a prior period.

Principle

With respect to all assets acquired before 1966, the provider, at its option, may choose an allowance for depreciation based on a percentage of operating costs. The operating costs to be used are the lower of the provider's 1965 operating costs or the provider's current year's allowable costs. The percent to be applied is 5 percent starting with the year 1966-67, with such percentage being uniformly reduced by one-half percent each succeeding year. The allowance based on operating costs is in addition to regular depreciation on assets acquired after 1965; however, when the optional allowance is selected, the combined amount of such allowance on pre-1966 assets and the allowance for actual depreciation on assets acquired after 1965 may not exceed 6 percent of the provider's allowable cost for the current year.

Definitions

Operating costs are the total costs incurred by the provider in operating the institution or facility.

Allowable costs are the costs of a provider which are includable under the principles for cost reimbursement; by the application of apportionment methods to the total amount of such allowable costs, the share of a provider's total cost which is attributable to covered services for beneficiaries is determined.

Comments

Where a provider has inadequate historical cost records for pre-1966 depreciable assets, the provider may elect to receive an allowance for depreciation on such assets based on a percentage of operating costs. The optional allowance for depreciation for such assets may be used, however, whether or not a provider has records of the cost of pre-1966 depreciable assets currently in use.

The allowance for depreciation based on a percentage of operating costs is to be computed by applying a specified percentage to a base amount equal to the provider's 1965 total operating costs, without adjustments to these principles, or the current year's allowable operating costs, whichever is lower. The percentage to be applied would be five for 1966-67, four and one-half for 1967-68, and would so continue to decline annually by equal amounts to become zero in 1976-77.

When used as a base for determining the optional allowance for depreciation, neither the 1965 operating costs nor the current year's allowable costs are to include any actual depreciation or estimated depreciation on rented depreciable-type assets. Such exclusions are

to be made only for the purpose of computing the allowance for depreciation based on operating costs. For other purposes, the excluded amounts are recognized in determining allowable costs and for computing the costs of services rendered to the program beneficiaries during the reporting period.

A provider that elects this allowance may at any time before 1976 change to actual depreciation on all pre-1966 depreciable assets. In such case, this option is eliminated and the provider can no longer elect to receive an allowance for depreciation based on a percentage of operating costs.

Where the provider desires to change to actual depreciation but either has no historical cost records or has incomplete records, the determination of historical cost could be made through appropriate means involving expert consultation with the determination being subject to review and approval by the intermediary.

The following illustrates how the provider would determine the optional allowance for depreciation based on operating costs.

Year 1966

The provider keeps its records on a calendar year basis. The current year's actual allowable cost and the actual operating cost for 1965 do not include any actual depreciation or rentals on depreciable-type assets.

Current year's allowable cost.....	\$1,100,000
Operating cost for 1965 ¹	\$1,000,000
Percent for determining the allowance.....	5

Allowance	\$50,000
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¹ 1965 operating cost was used in computing the allowance for depreciation based on a percentage of operating costs because it was lower than 1966 allowable cost.

Year 1967

Current year's allowable cost.....	\$1,200,000
Operating cost for 1965 ¹	\$1,000,000
Percent for determining the allowance.....	4½

Allowance	\$45,000
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¹ 1965 operating cost was used in computing the allowance for depreciation based on a percentage of operating costs because it was lower than 1967 allowable cost.

Year 1968

Operating cost for 1965.....	\$1,000,000
Current year's allowable cost ¹	\$900,000
Percent for determining the allowance.....	4

Allowance	\$36,000
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¹ The current year's allowable cost was used in computing the allowance for depreciation based on percentage of operating costs because it was lower than 1965 operating cost.

When the provider pays rent for depreciable-type assets rented prior to 1966, the estimated depreciation on such assets must be deducted from the allowance. The following illustration demonstrates how the allowance is determined.

Year 1966

The provider keeps its records on a calendar year basis. The current year's actual allowable cost and the actual operating cost for 1965 did not include any actual depreciation. However, such costs have been adjusted to exclude estimated depreciation on rented depreciable-type assets.

Adjusted current year's allowable cost.....	\$1,100,000
Adjusted operating cost for 1965 ¹	\$1,000,000
Percent for determining the allowance.....	5

Allowance	\$50,000
Less: Estimated depreciation for depreciable-type assets rented prior to 1966 on which rental is paid in 1966.....	\$3,000

Adjusted Allowance.....	\$47,000
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¹ 1965 operating cost was used in computing the allowance for depreciation based on a percentage of operating costs because it was lower than 1966 allowable cost.

Year 1967

Adjusted current year's allowable cost.....	\$1,200,000
Adjusted operating cost for 1965 ¹	\$1,000,000
Percent for determining the allowance.....	4½

Allowance	\$45,000
Less: Estimated depreciation for depreciable-type assets rented prior to 1966 on which rental is paid in 1967.....	\$3,000

Adjusted allowance.....	\$42,000
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¹ 1965 operating cost was used in computing the allowance for depreciation based on a percentage of operating costs because it was lower than 1967 allowable cost.

This optional allowance only is subject to a limitation based on the provider's total allowable operating cost for the current year. To determine this limitation, compute the sum of (1) the actual depreciation claimed, and (2) the allowance based on a percentage of operating costs after adjustment for estimated depreciation on depreciable-type assets rented after 1965. If this sum exceeds 6 percent of the provider's current year's allowable cost (exclusive of any actual depreciation claimed and estimated depreciation on rented depreciable-type assets), the allowance for depreciation based on a percentage of operating costs will be reduced by the amount of the excess. In applying this limitation, if the actual depreciation claimed is on an accelerated basis it must be converted to a straight-line basis only for use in calculating this limitation.

It is presumed that pre-1966 assets will not be retired at a greater than normal rate, and the limitation

of 6 percent, as it affects the availability of the allowance, is designed as a safeguard where the presumption is not borne out. Where the provider does not elect to use the optional allowance, the combined allowance for depreciation based on costs of pre-1966 assets and those subsequently acquired is not subject to the 6-percent limitation.

The following illustration demonstrates how this limitation would be determined.

Year 1966

The provider keeps its records on a calendar year basis. The current year's actual allowable cost and the actual operating cost for 1965 have been adjusted to exclude actual depreciation and the estimated depreciation on rented depreciable-type assets.

Adjusted operating cost for 1965.....	\$1,000,000
Percent for determining the allowance.....	5
In 1966 assets were acquired which produce a straight-line depreciation of.....	\$18,000
Estimated depreciation on assets rented in 1966.....	\$2,000
Adjusted allowable operating cost for 1966.....	\$1,100,000

CALCULATION OF ALLOWANCE FOR DEPRECIATION BASED ON A PERCENTAGE OF OPERATING COSTS

Gross allowance:	
5% × adjusted 1965 operating costs (\$1,000,000) ..	\$50,000
Estimated depreciation on assets rented in 1966.....	2,000
Straight-line depreciation on post-1965 assets.....	18,000

Total	\$70,000
6% of adjusted 1966 allowable operating cost.....	66,000

Deduction in allowance.....	\$4,000
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Allowance	\$50,000
Reduction	4,000

Adjusted allowance.....	\$46,000
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Total depreciation allowance for 1966 (\$18,000 actual depreciation plus \$46,000 allowance based on operating cost)	\$64,000
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Assume in this illustration that the provider had elected to use the declining balance method in computing its allowable depreciation and the rental expense for depreciable-type assets was \$3,500. In that case, it would include in its 1966 allowable cost not only the \$46,000 allowance based on operating costs but also \$36,000 (in this instance 2×straight-line rate is used) in actual depreciation and the rental expense of \$3,500—or a total of \$85,500 covering all its depreciable assets.

1-1C Allowance for Depreciation on Fully Depreciated or Partially Depreciated Assets

Principle

Depreciation on assets being used by a provider at the time it enters into the program will be allowed; this applies even though such assets may be fully or partially depreciated on the provider's books.

Comments

Depreciation is allowable on assets being used at the time the provider enters into the program. This applies even though such assets may be fully depreciated on the provider's books or fully depreciated with respect to other third-party payers. So long as an asset is being used, its useful life is considered not to have ended, and consequently the asset is subject to depreciation based upon a revised estimate of the asset's useful life as determined by the provider and approved by the intermediary. Correction of prior years' depreciation to reflect revision of estimated useful life should be made in the first year of participation in the program unless the provider has used the optional method (1-1B), in which case the correction should be made at

the time of discontinuing the use of that method. When an asset has become fully depreciated under the program, further depreciation would not be appropriate or allowable, even though the asset may continue in use.

For example, if a 50-year-old building is in use at the time the provider enters into the program, depreciation is allowable on the building, even though it has been fully depreciated on the provider's books. Assuming that a reasonable estimate of the asset's continued life is 20 years (70 years from the date of acquisition), the provider may claim depreciation over the next 20 years—if the asset is in use that long—or a total depreciation of as much as twenty-seventieths of the asset's historical cost. If the asset is disposed of before the expiration of its estimated useful life, the depreciation would be adjusted to the actual useful life.

Likewise, a provider may not have fully depreciated other assets it is using and finds that it has incorrectly estimated the useful lives of those assets. In such cases, the provider may use the corrected useful lives in determining the amount of depreciation, provided such corrections have been approved by the intermediary.

1-1D Allowance for Depreciation on Assets Financed With Federal or Public Funds

Principle

Depreciation will be allowed on assets financed with Hill-Burton or other Federal or public funds.

Comments

Like other assets (including other donated depreciable assets), assets financed with Hill-Burton or other Federal or public funds become a part of the provider institution's plant and equipment to be used in rendering services. It is the function of payment of depreciation to provide funds which make it possible to maintain the assets and preserve the capital employed in the production of services. Therefore, irrespective of the source of financing of an asset, if it is used in the providing of services for beneficiaries of the pro-

gram, payment for depreciation of the asset is, in fact, a cost of the production of those services. Moreover, recognition of this cost is necessary to maintain productive capacity for the future. An incentive for funding of depreciation is provided in these principles by the provision that investment income on funded depreciation will not be treated as a reduction of allowable interest expense under principle 1-2 which follows.

For certain purposes, however, assets financed with Hill-Burton or other Federal funds should be treated differently from other depreciable assets, i.e., such assets are to be excluded from the provider's net investment when applying the limitation on the allowance in lieu of specific recognition of other cost under principle 1-11.

1-2 Interest Expense

Principle

Necessary and proper interest on both current and capital indebtedness is an allowable cost.

Definitions

Interest is the cost incurred for the use of borrowed funds. Interest on current indebtedness is the cost incurred for funds borrowed for a relatively short term. This is usually for such purposes as working capital for normal operating expenses. Interest on capital indebtedness is the cost incurred for funds borrowed for capital purposes, such as acquisition of facilities and equipment, and capital improvements. Generally, loans for capital purposes are long-term loans.

Necessary requires that the interest:

- a. Be incurred on a loan made to satisfy a financial need of the provider. Loans which result in excess funds or investments would not be considered necessary.
- b. Be incurred on a loan made for a purpose reasonably related to patient care.
- c. Be reduced by investment income except where such income is from gifts and grants, whether restricted or unrestricted, and which are held separate and not commingled with other funds. Income from funded depreciation will not be used to reduce interest expense.

Proper requires that interest:

- a. Be incurred at a rate not in excess of what a prudent borrower would have had to pay in the money market existing at the time the loan was made.
- b. Be paid to a lender not related through control or ownership, or personal relationship to the borrowing organization. However, interest is allowable if paid on loans from the provider's donor-restricted funds or the funded depreciation account.

Comments

The congressional committee reports state that "reasonable cost" shall include necessary and proper interest on capital indebtedness. Historically this type of interest has not always been allowed as cost, so that special mention in the reports supports its allowance. Interest on current indebtedness, however, has been customarily considered an allowable cost by third-

party payers for health care. Generally, financing of business activities by judicious use of borrowed funds is an accepted and reasonable mode of operation and is recognized as such by this program.

To be allowable, interest expense must be incurred on indebtedness established with lenders or lending organizations not related through control, ownership, or personal relationship to the borrower. Presence of any of these factors could affect the "bargaining" process that usually accompanies the making of a loan, and could thus be suggestive of an agreement on higher rates of interest or of unnecessary loans. Loans should be made under terms and conditions that a prudent borrower would make in arms-length transactions with lending institutions. The intent of this provision is to assure that loans are legitimate and needed, and that the interest rate is reasonable.

Thus, interest paid by the provider to partners or to stockholders of the provider would not be allowable. Where the owner uses his own funds in a business, it is reasonable to treat the funds as invested funds or capital, rather than borrowed funds.

Exceptions to the general rule regarding interest on loans from controlled sources of funds are made in the following circumstances. Where the general fund of a provider "borrows" from a donor-restricted fund and pays interest to the restricted fund, this interest expense is an allowable cost. The same treatment will be accorded interest paid by the general fund on money "borrowed" from the funded depreciation account of the provider. In addition, if a provider operated by members of a religious order borrows from the order, interest paid to the order is an allowable cost.

Where funded depreciation is used for purposes other than improvement, replacement, or expansion of facilities or equipment related to patient care, allowable interest expense will be reduced to adjust for offsets not made in prior years for earnings on funded depreciation.

Allowable interest expense on current indebtedness of a provider will be adjusted to reflect the extent to which working capital needs which are attributable to covered services for beneficiaries have been met by payments to the provider designed to reimburse currently as services are furnished to beneficiaries.

1-3 Bad Debts, Charity, and Courtesy Allowances

Principle

Bad debts, charity, and courtesy allowances are deductions from revenue and are not to be included in allowable cost; however, bad debts attributable to the deductibles and coinsurance amounts are allowable costs.

Definitions

Bad debts are amounts considered to be uncollectible from accounts and notes receivable which were created or acquired in providing services. "Accounts receivable" and "notes receivable" are designations for claims arising from the rendering of services, and are collectible in money in the relatively near future.

Charity allowances are reductions in charges made by the provider of services because of the indigence or medical indigence of the patient.

Courtesy allowances indicate a reduction in charges in the form of an allowance to physicians, clergy, members of religious orders, and others as approved by the governing body of the provider, for services received from the provider. Employee fringe benefits, such as hospitalization and personnel health programs, are not considered to be courtesy allowances.

Comments

Bad debts, charity, and courtesy allowances represent reductions in revenue. The failure to collect charges for services rendered does not add to the cost of providing the services. Such costs have already been incurred in the production of the services.

Under Public Law 89-97, costs of covered services furnished beneficiaries are not to be borne by individuals not covered by the health insurance program, and conversely, costs of services provided for other than beneficiaries are not to be borne by the health insurance program. Uncollected revenue related to services rendered to beneficiaries of the program generally means

the provider has not recovered the cost of services covered by that revenue. The failure of beneficiaries to pay the deductible and coinsurance amounts can result in the related costs of covered services being borne by other than beneficiaries of the program. To assure that such covered service costs are not borne by others, the deductible and coinsurance amounts which remain unpaid will be included in the program's share of allowable costs. Bad debts arising from other sources are not allowable costs.

A bad debt must meet the following criteria to be allowable:

1. The debt must be related to covered services and derived from deductible and coinsurance amounts.
2. The provider must be able to establish that reasonable collection efforts were made.
3. The debt was actually uncollectible when claimed as worthless.
4. Sound business judgment established that there was no likelihood of recovery at any time in the future.

The amounts uncollectible from specific beneficiaries are to be charged off as bad debts in the accounting period in which the accounts are deemed to be worthless. In some cases an amount previously written off as a bad debt and allocated to the program may be recovered in a subsequent accounting period; in such cases the income therefrom must be used to reduce the cost of beneficiary services for the period in which the collection is made.

Charity allowances have no relationship to beneficiaries of the health insurance program and are not allowable costs.

The cost to the provider of employee fringe-benefit programs is an allowable element of reimbursement.

1-4 Cost of Educational Activities

Principle

An appropriate part of the net cost of approved educational activities is an allowable cost.

Definitions

Approved educational activities means formally organized or planned programs of study usually engaged in by providers in order to enhance the quality of patient care in an institution. These activities must be licensed where required by State law. Where licensing is not required, the institution must receive approval from the recognized national professional organization for the particular activity.

The net cost means the cost of approved educational activities (including stipends of trainees, compensation of teachers, and other costs), less any reimbursements from grants, tuition, and specific donations.

The appropriate part means the net cost of the activity apportioned in accordance with the methods set forth in these principles.

Comments

Many providers engage in educational activities including training programs for nurses, medical students, interns and residents, and various paramedical specialties. These programs contribute to the quality of patient care within an institution and are necessary to meet the community's needs for medical and paramedical personnel.

The congressional committee reports make clear that it was the intent of Congress that a part of the net cost of educational activities should be considered an element in the cost of patient care, to be borne to an appropriate extent by the health insurance program.

It is recognized that the costs of such educational activities should be borne by the community. However, many communities have not assumed responsibility for financing these programs and it is necessary that support be provided by those purchasing health care. Until communities undertake to bear these costs, the program will participate appropriately in the support of these activities. Although the intent of the program is to share in the support of educational activities customarily or traditionally carried on by providers in conjunction with their operations, it is not intended that this program should participate in increased costs resulting from redistribution of costs from educational institutions or units to patient care institutions or units.

The costs of "orientation" and "on-the-job training" are not within the scope of this principle but are recognized as normal operating costs in accordance with principles relating thereto.

In addition to approved medical, osteopathic, and dental internships and residency programs, recognized professional and paramedical educational and training programs now being conducted by provider institutions, and their approving bodies, include the following:

Program	Approving bodies
1. Cytotechnology -----	Council on Medical Education of the American Medical Association in collaboration with the Board of Schools of Medical Technology of the American Society of Clinical Pathologists.
2. Dietetic internships-----	The American Dietetic Association.
3. Hospital administration residencies	Members of the Association of University Programs in Hospital Administration.
4. Inhalation therapy-----	Council on Medical Education of the American Medical Association in collaboration with the Board of Schools of Inhalation Therapy.
5. Medical records-----	Council on Medical Education of the American Medical Association in collaboration with the Committee on Education and Registration of the American Association of Medical Record Librarians.
6. Medical technology-----	Council on Medical Education of the American Medical Association in collaboration with the Board of Schools of Medical Technology, American Society of Clinical Pathologists.
7. Nurse anesthetists-----	The American Association of Nurse Anesthetists.
8. Professional nursing-----	Approved by the respective State approving authorities. Reported for the United States by the National League for Nursing.
9. Practical nursing-----	Approved by the respective State approving authorities. Reported for the United States by the National League for Nursing.
10. Occupational therapy----	Council on Medical Education of the American Medical Association in collaboration with the Council on Education of the American Occupational Therapy Association.

<i>Program</i>	<i>Approving bodies</i>
11. Pharmacy internships and residencies	Accredited by the American Council on Pharmaceutical Education.
12. Physical therapy-----	Council on Medical Education of the American Medical Association in collaboration with the American Physical Therapy Association.
13. X-ray technology-----	Council on Medical Education of the American Medical Association in collaboration with the American College of Radiology.

There may also be other educational programs not included in the foregoing in which a provider institution is engaged. Appropriate consideration will be given by the intermediary and the Social Security Administration to the costs incurred for those activities that come within the purview of the principle when determining the allowable costs for apportionment under the health insurance program.

1-5 Research Costs

Principle

Costs incurred for research purposes, over and above usual patient care, are not includable as allowable costs.

Comment

There are numerous sources of financing for health-related research activities. Funds for this purpose are provided under many Federal programs and by other tax-supported agencies. Also, many foundations, voluntary health agencies, and other private organizations, as well as individuals, sponsor or contribute to the support of medical and related research. Funds available from such sources are generally ample to meet basic medical and hospital research needs.

A further consideration is that quality review should be assured as a condition of governmental support for research. Provisions for such review would introduce special difficulties in the health insurance program.

Where research is conducted in conjunction with and as a part of the care of patients, the costs of usual patient care are allowable to the extent that such costs are not met by funds provided for the research.

Under this principle, however, studies, analyses, surveys, and related activities to serve the provider's administrative and program needs, are not excluded as allowable costs in the determination of reimbursement under the program.

1-6 Grants, Gifts, and Income From Endowments

Principle

Unrestricted grants, gifts, and income from endowments should not be deducted from operating costs in computing reimbursable cost. Grants, gifts, or endowment income designated by a donor for paying specific operating costs should be deducted from the particular operating cost or group of costs.

Definitions

Unrestricted grants, gifts, and income from endowments are funds, cash or otherwise, given to a provider without restriction by the donor as to their use.

Designated or restricted grants, gifts, and income from endowments are funds, cash or otherwise, which must be used only for the specific purpose designated by the donor. This does not refer to unrestricted grants, gifts, or income from endowments which have been restricted for a specific purpose by the provider.

Comments

Unrestricted funds, cash or otherwise, are generally the property of the provider to be used in any manner its management deems appropriate and should not be deducted from operating costs. It would be inequitable to require providers to use the unrestricted funds to reduce the payments for care. The use of these funds is generally a means of recovering costs which are not otherwise recoverable.

Donor-restricted funds which are designated for paying certain hospital operating expenses should apply and serve to reduce these costs or group of costs and benefit all patients who use services covered by the donation. If such costs are not reduced, the provider would secure reimbursement for the same expense twice; it would be reimbursed through the donor-restricted contributions as well as from patients and third-party payers including the health insurance program.

1-7 Value of Voluntary Services

Principle

The value of voluntary services provided by sisters or other members of religious orders is allowable as an operating expense for the determination of allowable cost. The amounts included are not to exceed those paid others for similar work. Such amounts must be identifiable in the records of the institution as a legal obligation for operating expenses.

Definitions

Voluntary services must be performed by sisters or other members of religious orders in positions necessary to enable the provider institution to carry out the functions of normal patient care. The value of donated services of individual volunteers or members of volunteer organizations engaged in various activities at a provider institution is not allowable as a reimbursable cost under the health insurance program.

Comments

Equity of treatment among providers of services

requires that an amount equal to the value of the services rendered by members of religious orders be allowable as a cost. To do otherwise could result in provider institutions operated entirely by religious orders showing unrealistic costs.

The following illustrates how a provider would determine an amount to be allowed under this principle: The prevailing salary for a lay nurse working in Hospital A is \$5,000 for the year. The lay nurse receives no maintenance or special perquisites. A sister working as a nurse engaged in the same activities in the same hospital receives maintenance and special perquisites which cost the hospital \$2,000 and are included in the hospital's allowable operating costs. The hospital would then include in its records an additional \$3,000 to bring the value of the services rendered to \$5,000. The amount of \$3,000 would be allowable where the provider assumes obligation for the expense under a written agreement with the sisterhood or other religious order covering payment by the provider for the services.

1-8 Purchase Discounts and Allowances, and Refunds of Expenses

Principle

Discounts and allowances received on purchases of goods or services are reductions of the costs to which they relate. Similarly, refunds of previous expense payments are reductions of the related expense.

Definitions

Discounts, in general, are reductions granted for the settlement of debts.

Allowances are deductions granted for damage, delay, shortage, imperfection or other causes, excluding discounts and returns.

Refunds are amounts paid back or a credit allowed on account of an overcollection.

All discounts, allowances, and refunds of expenses are reductions in the cost of goods or services purchased and are not income. When they are received in the same accounting period in which the purchases were made or expenses were incurred, they will reduce the purchases or expenses of that period. However, when they are received in a later accounting period, they will reduce the comparable purchases or expenses in the period in which they are received.

Comments

Purchase discounts have been classified as cash, trade, or quantity discounts. Cash discounts are reductions

granted for the settlement of debts before they are due. Trade discounts are reductions from list prices granted to a class of customers before consideration of credit terms. Quantity discounts are reductions from list prices granted because of the size of individual or aggregate purchase transactions. Whatever the classification of purchase discounts, like treatment in reducing allowable costs is required.

In the past, purchase discounts were considered as financial management income. However, modern accounting theory holds that income is not derived from a purchase but rather from a sale or an exchange and that purchase discounts are reductions in the cost of whatever was purchased. The true cost of the goods or services is the net amount actually paid for them. Treating purchase discounts as income would result in an overstatement of costs to the extent of the discount.

As with discounts, allowances, and rebates received from purchases of goods or services and refunds of previous expense payments are clearly reductions in costs and must be reflected in the determination of allowable costs. This treatment is equitable and is in accord with that generally followed by other governmental programs and third-party payment organizations paying on the basis of cost.

1-9 Compensation of Owners

Principle

A reasonable allowance of compensation for services of owners is an allowable cost, provided the services are actually performed in a necessary function.

Definitions

Compensation means the total benefit received by the owner for the services he renders to the institution. It includes:

- a. Salary amounts paid for managerial, administrative, professional, and other services.
- b. Amounts paid by the institution for the personal benefit of the proprietor.
- c. The cost of assets and services which the proprietor receives from the institution.
- d. Deferred compensation.

Reasonableness requires that the compensation allowance:

- a. Be such an amount as would ordinarily be paid for comparable services by comparable institutions.
- b. Depend upon the facts and circumstances of each case.

Necessary requires that the function:

- a. Be such that had the owner not rendered the services, the institution would have had to employ another person to perform the services.
- b. Be pertinent to the operation and sound conduct of the institution.

Comments

Owners of provider organizations often render services as managers, administrators, or in other capacities. In such cases, it is equitable that reasonable compensation for the services rendered be an allowable cost. To do otherwise would disadvantage such owners in comparison with corporate providers or providers employing persons to perform similar services.

Ordinarily, compensation paid to proprietors is a distribution of profits. However, where a proprietor renders necessary services for the institution, the institution is in effect employing his services, and a reasonable compensation for these services is an allowable cost. In corporate providers, the salaries of owners who are also employees are subject to the same requirements of reasonableness. Where the services are rendered on less than a full-time basis, the allowable compensation should reflect an amount proportionate to a full-time basis. Reasonableness of compensation may be determined by reference to, or in comparison with, compensation paid for comparable services and responsibilities in comparable institutions; or it may be determined by other appropriate means.

Third-party payers using cost-related formulas for reimbursement treat compensation of owners in several ways such as: not allowed; allowed if reasonable and essential; allowed and based on bed capacity; allowed if in line with nonprofit institutions. Third-party payers that treat owners' compensation as an allowable cost require, in effect, that the compensation be reasonable and the services necessary.

1-10 Cost to Related Organizations

Principle

Costs applicable to services, facilities, and supplies furnished to the provider by organizations related to the provider by common ownership or control are includable in the allowable cost of the provider at the cost to the related organization. However, such cost must not exceed the price of comparable services, facilities, or supplies that could be purchased elsewhere.

Definitions

Related to the provider means that the provider to a significant extent is associated or affiliated with or has control of or is controlled by the organization furnishing the services, facilities, or supplies.

Common ownership exists when an individual or individuals possess significant ownership or equity in the provider and the institution or organization serving the provider.

Control exists where an individual or an organization has the power, directly or indirectly, significantly to influence or direct the actions or policies of an organization or institution.

Comments

Individuals and organizations associate with others for various reasons and by various means. Some deem it appropriate to do so to assure a steady flow of supplies or services, to reduce competition, to gain a tax advantage, to extend influence, and for other reasons. These goals may be accomplished by means of ownership or control, by financial assistance, by management assistance, and other ways.

Where the provider obtains items of services, facilities, or supplies from an organization, even though it is a separate legal entity, and the organization is owned or controlled by the owner(s) of the provider, in effect the items are obtained from itself. An example would be a corporation building a hospital or a nursing home and then leasing it to another corporation controlled by the owner.

Therefore, reimbursable cost should include the costs for these items at the cost to the supplying organization. However, if the comparable services, facilities, or supplies could be obtained at a lower cost elsewhere, the "going rates" should be the amount includable by the provider as a reasonable allowable cost.

1-11 Allowance in Lieu of Specific Recognition of Other Costs

Principle

In lieu of specific recognition of other costs in providing and improving services, an allowance amounting to 2 percent of costs allowed under the other principles (with the exception of interest expense) is includable as an element of reasonable cost of services, subject to the limitation that the allowance not exceed a reasonable long-term interest rate on the provider's net investment related to patient care.

Comments

Difficulty in measurement, lack of adequate data and other considerations have precluded specific recognition of various elements which are germane to costs of services for beneficiaries. Moreover, although the methods to be utilized by providers for determining the actual cost of services provided to beneficiaries are the best available, there is some lack of precision in methods at the present stage of development of cost finding which represents a contingency for which recognition is appropriate. It is the established practice of a

significant number of large third-party purchasers to include in payment for costs of services a factor in the form of an allowance to cover various elements not specifically recognized or not precisely measured.

This allowance is, in part, in lieu of a specific interest return on equity capital as well as other factors not given specific recognition. The allowance under this principle is limited to an amount which, as a percentage of the provider's investment in plant, property, and equipment related to patient care (net of depreciation and long-term debt related to such investment), does not exceed the average interest rate on special issues of public-debt obligations issued to the Federal Hospital Insurance Trust Fund during the reporting period (i.e., the appropriate average of the several monthly rates, as determined under section 1817(c) of the Social Security Act). In the determination of the amount of the provider's net investment, for purposes of applying this limitation, the cost of assets financed by Hill-Burton or other Federal funds will be excluded. Such exclusion will be on the basis of the share of the cost financed by Federal funds after adjustment for depreciation.



GENERAL PRINCIPLES OF REIMBURSEMENT

2-1 Costs Related to Patient Care

Principle

All payments to providers of services must be based on the "reasonable cost" of services covered under Public Law 89-97 and related to the care of beneficiaries. Reasonable cost includes all necessary and proper costs incurred in rendering the services, subject to principles relating to specific items of revenue and cost.

Definitions

Reasonable cost of any services must be determined in accordance with regulations establishing the method or methods to be used, and the items to be included. These regulations take into account both direct and indirect costs of providers of services. The objective is that under the methods of determining costs, the costs with respect to individuals covered by the program will not be borne by individuals not so covered, and the costs with respect to individuals not so covered will not be borne by the program. The regulations also provide for the making of suitable retroactive adjustments after the provider has submitted fiscal and statistical reports. The retroactive adjustment will represent the difference between the amount received by the provider during the year for covered services from both the program and the beneficiaries and the amount determined in accordance with an accepted method of cost apportionment to be the actual cost of services rendered to beneficiaries during the year.

Necessary and proper costs are costs which are appropriate and helpful in developing and maintaining the operation of patient care facilities and activities. They are usually costs which are common and accepted occurrences in the field of the provider's activity.

Comments

It is the intent of the law that payments to providers of services should be fair to the providers, to the contributors to the health-insurance trust funds, and to other patients.

The costs of providers' services vary from one provider to another and the variations generally reflect differences in scope of services and intensity of care. The provision in the law for payment of reasonable cost of services is intended to meet the actual costs, however widely they may vary from one institution to another. This is subject to a limitation where a particular institution's costs are found to be substantially out of line with other institutions in the same area which are similar in size, scope of services, utilization, and other relevant factors.

The determination of reasonable cost of services must be based on costs related to the care of beneficiaries of the program. Reasonable cost includes all necessary and proper expenses incurred in rendering services, such as administrative costs, maintenance costs, and premium payments for employee health and pension plans. It includes both direct and indirect costs and normal standby costs. However, where the provider's operating costs include amounts not related to patient care, or specifically not reimbursable under the program, such amounts will not be allowable.

The reasonable cost basis of reimbursement contemplates that the providers of services would be reimbursed the actual costs of providing quality care however widely the actual costs may vary from provider to provider and from time to time for the same provider.

2-2 Determination of Cost of Services to Beneficiaries

Principle

Total allowable costs of a provider shall be apportioned between program beneficiaries and other patients so that the share borne by the program is based upon actual services received by program beneficiaries. To accomplish this apportionment, the provider shall have the option of either of the two following methods: (1) Departmental method—the ratio of beneficiary charges to total patient charges for the services of each department is applied to the cost of the department; (2) Combination method—the cost of “routine services” for program beneficiaries is determined on the basis of average cost per diem of these services for all patients; to this is added the cost of ancillary services used by beneficiaries, determined by apportioning the total cost of ancillary services on the basis of the ratio of beneficiary charges for ancillary services to total patient charges for such services.

Definitions

Apportionment means an allocation or distribution of allowable cost between the beneficiaries of the health insurance program and other patients.

Routine services means the regular room, dietary, and nursing services, minor medical and surgical supplies and the use of equipment and facilities for which a separate charge is not customarily made.

Ancillary services or special services are the services for which charges are customarily made in addition to routine services.

Charges refers to the regular rates for various services which are charged to both beneficiaries and other paying patients who receive the services. Implicit in the use of charges as the basis for apportionment is the objective that charges for services be related to the cost of the services.

Cost refers to reasonable cost as described in principle 2-1.

Ratio of beneficiary charges to total charges on a departmental basis, as applied to inpatients, means the ratio of inpatient charges to beneficiaries of the health insurance program for services of a revenue-producing department or center to the inpatient charges to all patients for that center during an accounting period. After each revenue-producing center's ratio is determined, the cost of services rendered to beneficiaries of the health insurance program is computed by apply-

ing the individual ratio for the center to the cost of the related center for the period.

Average cost per diem for routine services means the amount computed by dividing the total allowable inpatient cost for routine services by the total number of inpatient days of care (excluding newborn days where nursery costs are excluded from routine service costs) rendered by the provider in the accounting period.

Ratio of beneficiary charges for ancillary services to total charges for ancillary services, as applied to inpatients, means the ratio of the total inpatient charges for covered ancillary services rendered to beneficiaries of the health insurance program to the total inpatient charges for ancillary services to all patients during an accounting period. This ratio is applied to the allowable inpatient ancillary costs for the period to determine the amount of reimbursement to a provider for the covered ancillary services rendered to beneficiaries.

Comments

The law provides that the costs with respect to individuals covered by the health insurance program will not be borne by individuals not so covered, and, conversely, that costs with respect to individuals who are not under the program will not be borne by the program.

The cost of services to beneficiaries of the health insurance program may be determined by either of the alternative methods that is selected by a provider; however, the objective of whatever method of apportionment is used will be to approximate as closely as practicable the actual cost of services rendered.

The two methods of apportionment available for use in determining the cost of services rendered to beneficiaries of the program have as their goal the allocation of the total allowable costs between the beneficiaries and other patients in as equitable a manner as possible. Under these methods, if it is found that beneficiaries receive more than the average amount of services, the providers would receive reimbursement greater than average cost for all patients. Conversely, if the beneficiaries receive less than the average amount of services, the providers would be reimbursed accordingly for the services rendered.

Departmental Method

The following illustrates how apportionment based on the ratio of beneficiary charges to total charges applied to cost on a departmental basis would be determined, using only inpatient data.

Hospital A

Department	Charges to program beneficiaries	Total charges	Ratio of beneficiary charges to total charges	Total cost	Cost of beneficiary services
			<i>Percent</i>		
Routine services.....	\$140,000	\$600,000	23½%	\$630,000	\$147,000
X-ray.....	24,000	100,000	24	75,000	18,000
Operating room.....	20,000	70,000	28½%	77,000	22,000
Laboratory.....	40,000	140,000	28½%	98,000	28,000
Pharmacy.....	20,000	60,000	33½%	45,000	15,000
Others.....	6,000	30,000	20	25,000	5,000
Total.....	\$250,000	\$1,000,000		\$950,000	\$235,000

The total reimbursement for services rendered by the provider to the beneficiaries would be \$235,000.

Combination Method

A provider may, at its option, elect to be reimbursed on the average cost per diem for the cost of routine services, with apportionment of the cost of ancillary services on the basis of the ratio of beneficiary charges to total patient charges applied to the cost of all such ancillary services. The cost of the ancillary services rendered to beneficiaries of the program is determined by computing the ratio of total inpatient charges for ancillary services to beneficiaries to the total inpatient ancillary charges to all patients. This ratio is then applied to the total allowable cost of inpatient ancillary services.

Estimated Percentages

The provider has an option at the beginning of the program of obtaining from the intermediary and utilizing an estimated rather than a computed basis for apportioning cost between routine and ancillary services.

Where a provider either elects this option or is unable to make the necessary computations by cost-finding methods as indicated in Principle 2-3, the intermediary will estimate the appropriate percentage of the provider's allowable cost that represents routine service costs and the appropriate percentage that represents the ancillary service costs. These percentages are to be based upon study, analysis, and judgment by the intermediary and designed to approximate the result that a cost-finding method would have produced for the particular provider.

The use of estimated percentages would apply only to cost reports for periods ending before January 1, 1968. For subsequent periods, the use of cost-finding methods as described in Principle 2-3 will be required for the apportionment of allowable costs.

The following illustrates how apportionment under this method would be determined.

Cost Finding Employed by Hospital B

Statistical and financial data:

Total inpatient days for all patients.....	30,000
Inpatient days applicable to beneficiaries.....	7,500
Inpatient routine services—total allowable cost.....	\$600,000
Inpatient ancillary services—total allowable cost.....	\$320,000
Inpatient ancillary services—total charges.....	\$400,000
Inpatient ancillary services—charges for services to beneficiaries.....	\$80,000
Computation of cost applicable to program:	
Average cost per diem for routine services: \$600,000 ÷ 30,000 days = \$20 per diem	
Cost of routine services rendered to beneficiaries: \$20 per diem × 7,500 days.....	\$150,000
Ratio of beneficiary charges to total charges for all ancillary services:	
\$80,000 ÷ \$400,000 = 20%	
Cost of ancillary services rendered to beneficiaries: 20% × \$320,000.....	\$64,000
Total cost of beneficiary services.....	\$214,000

Estimated Percentages Employed by Hospital C

Statistical and financial data:

Total inpatient days for all patients.....	35,000
Inpatient days applicable to beneficiaries.....	5,000
Total allowable inpatient cost.....	\$1,000,000
Estimated percent for routine inpatient services.....	70
Estimated percent for ancillary inpatient services.....	30
Inpatient ancillary services:	
Total charges.....	\$400,000
Charges for services to beneficiaries.....	\$80,000
Computation of cost applicable to program:	
Average cost per diem for routine services: 70% × \$1,000,000 = \$700,000 (routine service cost)	
\$700,000 ÷ 35,000 days = \$20 per diem	
Cost of routine services rendered to beneficiaries: \$20 per diem × 5,000 days.....	\$100,000
Ratio of beneficiary charges to total charges for all ancillary services:	
\$80,000 ÷ \$400,000 = 20%	
Cost of ancillary services rendered to beneficiaries:	
30% × \$1,000,000 = \$300,000 (ancillary service cost)	
20% × \$300,000.....	\$60,000
Total cost of beneficiary services.....	\$160,000

The provider has the option of using either the departmental method or the combination method for the first reporting period. Thereafter, a provider may change from one to the other method provided a request is made to the intermediary before the end of the first month of the period for which the change is to be applied and such request is approved.

Temporary Methods of Apportionment

The intermediary may find that a provider is unable to apply either the departmental method or the combination method employing cost finding or estimated percentages. In such case, the intermediary can authorize the provider to use, on a temporary basis, an apportionment based on the ratio of beneficiary inpatient charges to total inpatient charges applied to the total cost of all services. This would permit the provider time to establish the records necessary for applying either of the basic alternative methods of apportionment in the next accounting period. In some cases the intermediary may determine that a provider is unable to employ this temporary method of apportionment based on the ratio of beneficiary inpatient charges to total inpatient charges applied to total inpatient cost. In such a case any other method determined by the intermediary to be

reasonable may be used on a temporary basis. Any temporary method of apportionment may not be used to cover more than one cost reporting period.

The following illustration demonstrates the apportionment of cost based on the ratio of beneficiary inpatient charges to all inpatient charges computed on a total basis for all inpatient services.

Hospital D

Financial data:

Inpatient services:	
Total allowable cost.....	\$950,000
Total charges.....	1,000,000
Charges for beneficiary services.....	200,000

Computation of cost of beneficiary inpatient services:

Ratio of beneficiary charges to total charges:	
$\$200,000 \div \$1,000,000 = 20\%$	
Cost of services rendered to beneficiaries:	
20% \times \$950,000	\$190,000

Whenever authorization is given to apportion costs by a method other than one of the two basic alternative methods, such authorization would be considered to be a temporary expediency to cover only one accounting period. It would be available to a provider only after diligent efforts have been made by the provider to apportion its costs based upon either of the approved methods of apportionment.

2-3 Adequate Cost Data and Cost Finding

Principle

Providers receiving payment on the basis of reimbursable cost must provide adequate cost data. This must be based on their financial and statistical records which must be capable of verification by qualified auditors. The cost data must be based on an approved method of cost finding and on the accrual basis of accounting. However, where governmental institutions operate on a cash basis of accounting, cost data based on such basis of accounting will be acceptable, subject to appropriate treatment of capital expenditures.

Definitions

Cost finding is the process of recasting the data derived from the accounts ordinarily kept by a provider to ascertain costs of the various types of services rendered. It is the determination of these costs by the allocation of direct costs and proration of indirect costs.

Under the *accrual basis of accounting*, revenue is reported in the period when it is earned, regardless of when it is collected, and expenses are reported in the period in which they are incurred, regardless of when they are paid.

Comments

Adequate cost information must be obtained from the provider's records to support payments made for services rendered to beneficiaries. The requirement of adequacy of data implies that the data be accurate and in sufficient detail to accomplish the purposes for which it is intended. Adequate data capable of being audited is consistent with good business concepts and effective and efficient management of any organization, whether it is operated for profit or on a nonprofit basis. It is a reasonable expectation on the part of any agency paying for services on a cost-reimbursement basis.

In order to provide the required cost data and not impair comparability, financial and statistical records should be maintained in a manner consistent from one period to another. However, a proper regard for consistency need not preclude a desirable change in accounting procedures when there is reason to effect such change.

After the close of the accounting period, one of the following methods of cost finding is to be used to determine the actual costs of services rendered during that period.

Step-down Method

This method recognizes that services rendered by certain nonrevenue-producing departments or centers are utilized by certain other nonrevenue-producing centers as well as by the revenue-producing centers. All costs of nonrevenue-producing centers are allocated to all centers which they serve, regardless of whether or not these centers produce revenue. The cost of the nonrevenue-producing center serving the greatest number of other centers, while receiving benefits from the least number of centers, is apportioned first. Following the apportionment of the cost of the nonrevenue-producing center, that center will be considered "closed" and no further costs are apportioned to that center. This applies even though it may have received some service from a center whose cost is apportioned later. Generally when two centers render service to an equal number of centers while receiving benefits from an equal number, that center which has the greatest amount to expense should be allocated first.

Other Methods

The double-apportionment method may be used by a provider upon approval of the intermediary. This method also recognizes that the nonrevenue-producing departments or centers render services to other nonrevenue-producing centers as well as to revenue-producing centers. A preliminary allocation of the costs of nonrevenue-producing centers is made. These centers or departments are not "closed" after this preliminary allocation. Instead, they remain "open," accumulating a portion of the costs of all other centers from which services are received. Thus, after the first or preliminary allocation, some costs will remain in each center representing services received from other centers. The first or preliminary allocation is followed by a second or final apportionment of expenses involving the allocation of all costs remaining in the nonrevenue-producing functions directly to revenue-producing centers.

A more sophisticated method designed to allocate costs more accurately may be used by the provider upon approval of the intermediary. However, having elected to use the double-apportionment method, the provider may not thereafter use the step-down method without approval of the intermediary. Request for the approval must be made on a prospective basis and must be submitted before the end of the first month of the

prospective reporting period. Likewise, once having elected to use a more sophisticated method, the provider may not thereafter use either the double-apportionment or step-down methods without similar request and approval.

Temporary Method for Initial Period

If the provider is unable to use either cost-finding method when it first participates in the program, it may apply to the intermediary for permission to use some other acceptable method which would accurately identify costs by department or center, and appropriately

segregate inpatient and outpatient costs. Such other method may be used for cost reports covering periods ending before January 1, 1968.

Accounting Basis

The cost data submitted must be based on the accrual basis of accounting which is recognized as the most accurate basis for determining costs. However, governmental institutions that operate on a cash basis of accounting may submit cost data on the cash basis subject to appropriate treatment of capital expenditures.

2-4 Payments to Providers

Principle

Providers of services will be paid the reasonable cost of services furnished to beneficiaries. Interim payments approximating the actual costs of the provider will be made on the most expeditious basis administratively feasible but not less often than monthly. A retroactive adjustment based on actual costs will be made at the end of the reporting period. At the request of the provider, payment will be made on a basis designed to reimburse concurrently as services are rendered to beneficiaries.

Comments

The law states that providers of services will be paid the reasonable cost of services furnished to beneficiaries. Since actual costs of services cannot be determined until the end of the accounting period, the providers must be paid on an estimated cost basis during the year. While the law provides that interim payments shall be made no less often than monthly, intermediaries are expected to make payments on the most expeditious basis administratively feasible. Whatever estimated cost basis is used for determining interim payments during the year, the intent is that the interim payments shall approximate actual costs as nearly as is practicable so that the retroactive adjustment based on actual costs will be as small as possible.

Interim Payments During Initial Reporting Period

At the beginning of the program or when a provider first participates in the program, it will be necessary to establish interim rates of payment to providers of services. Once a provider has filed a cost report under the health insurance program, the cost report may be used as a basis for determining the interim rate of reimbursement for the following period. However, since initially there is no previous history of cost under the program, the interim rate of payment must be determined by other methods, including the following:

1. Where the intermediary is already paying the provider on a cost or cost-related basis, the intermediary will adjust its rate of payment to the program's principles of reimbursement. This rate may be either an amount per inpatient day, or a percent of the provider's charges for services rendered to the program's beneficiaries.
2. Where an organization other than the intermediary is paying the provider for services on a cost or cost-related basis, the intermediary may obtain from that organization or from the

provider itself the rate of payment being used and other cost information as may be needed to adjust that rate of payment to give recognition to the program's principles of reimbursement.

3. Where no organization is paying the provider on a cost or cost-related basis, the intermediary will obtain the previous year's financial statement from the provider. By analysis of such statement in the light of the principles of reimbursement, the intermediary will compute an appropriate rate of payment.

After the initial interim rate has been set, the provider may at any time request, and be allowed, an appropriate increase in the computed rate, upon presentation of satisfactory evidence to the intermediary that costs have increased. Likewise, the intermediary may adjust the interim rate of payment if it has evidence that actual costs may fall significantly below the computed rate.

Interim Payments for New Providers

Newly established providers will not have a cost experience on which to base a determination of an interim rate of payment. In such cases, the intermediary will use the following methods to determine an appropriate rate:

1. Where there is a provider or providers comparable in substantially all relevant factors to the provider for which the rate is needed, the intermediary will base an interim rate of payment on the costs of the comparable provider.
2. If there are no substantially comparable providers from whom data are available, the intermediary will determine an interim rate of payment based on the budgeted or projected costs of the provider.

Under either method, the intermediary will review the provider's cost experience after a period of three months. If need for an adjustment is indicated, the interim rate of payment will be adjusted in line with the provider's cost experience.

Interim Payments After Initial Reporting Period

Interim rates of payment for services provided after the initial reporting period will be established on the basis of the cost report filed for the previous year covering health insurance services. The current rate will be determined—whether on a per diem or percentage of charges basis—using the previous year's costs of

covered services and making any appropriate adjustments required to bring, as closely as possible, the current year's rate of interim payment into alignment with current year's costs.

This interim rate of payment may be adjusted by the intermediary during an accounting period if the provider submits appropriate evidence that its actual costs are or will be significantly higher than the computed rate. Likewise, the intermediary may adjust the interim rate of payment if it has evidence that actual costs may fall significantly below the computed rate.

Retroactive Adjustment

The law provides that providers of services shall be paid amounts determined to be due, but not less often than monthly, with necessary adjustments due to previously made overpayments or underpayments. Interim payments are made on the basis of estimated costs. Actual costs reimbursable to a provider cannot be determined until the cost reports are filed and costs are verified. Therefore, a retroactive adjustment will be made at the end of the reporting period to bring the interim payments made to the provider during the period into agreement with the reimbursable amount payable to the provider for the services rendered to program beneficiaries during that period.

In order to reimburse the provider as quickly as possible, an initial retroactive adjustment will be made as soon as the cost report is received. For this purpose, the costs will be accepted as reported—unless there are obvious errors or inconsistencies—subject to later audit. When an audit is made and the final liability of the program is determined, a final adjustment will be made.

To determine the retroactive adjustment, the amount of the provider's total allowable cost apportioned to the program for the reporting year is computed. This is the total amount of reimbursement the provider is due

to receive from the program and the beneficiaries for covered services rendered during the reporting period. The total of the interim payments made by the program in the reporting year and the deductibles and coinsurance amounts receivable from beneficiaries is computed. The difference between the reimbursement due and the payments made is the amount of the retroactive adjustment.

Provision for Current Financing

In addition to the basic procedure for payment to a provider following the submission of bills to the intermediary, payment will be made upon request by the provider on a basis designed to reimburse concurrently as services are furnished to beneficiaries. The amount of such payment will be computed by the intermediary initially on an estimated basis and periodically adjusted to represent the average level of services unreimbursed by the basic payment procedure.

A study will be made of the possibility that a financial requirement in the production of services arises prior to the rendition of services to beneficiaries and is not being met by the program. Among the factors to be considered in the study will be the extent to which outlays for consumable items for which payment may be made in advance of rendition of services are offset by outlays for other items, such as wages and salaries, which ordinarily are not made until after services are rendered.

Cost Reporting Period

For cost-reporting purposes, the program will require submission of annual reports covering a 12-month period of operations based upon the provider's accounting year. At the option of the provider, however, during the first year of the program a short period report beginning July 1, 1966, and ending with the provider's accounting year may be submitted, provided such report covers at least 6 months.







HEALTH INSURANCE FOR THE AGED

**PRINCIPLES OF REIMBURSEMENT
FOR
PROVIDER COSTS**

U.S. DEPARTMENT OF
HEALTH, EDUCATION, AND WELFARE
SOCIAL SECURITY ADMINISTRATION
HIM-5 (Revised)

March 1967

Revision Transmittal No. 1

Please make the following corrections:

Page 7 Column 2 Line 3: Change "recognization" to recognition".

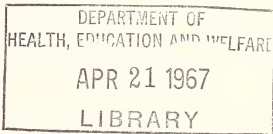
Page 8 Column 1-
Principle 1-1B . Last Line: Change "Deduction" to "Reduction".

Page 16 Column 2 Line 17: Change "additiional" to "additional".

Page 20 Column 2 Line 5: Change "percision" to "precision".

Page 23 Column 1 Line 4: Change "tite" to "title".

Page 29 Column 1 Line 44: Change "pogram's" to "program's".





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**HEALTH
INSURANCE
FOR THE AGED**

**PRINCIPLES OF
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FOR PROVIDER
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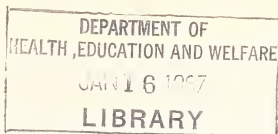
U.S. DEPARTMENT OF
HEALTH, EDUCATION, AND WELFARE
SOCIAL SECURITY ADMINISTRATION

HIM-5 (REVISED 1-67)

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*AUTHORITY: 20 CFR 405, §§ 405.401-405.454 issued under secs. 1102, 1814(b), 1861(v), and 1871, 49 Stat. 647, as amended, 79 Stat. 296, 79 Stat. 322, 79 Stat. 331; 42 U.S.C. 1302, 1395 et seq.



PRINCIPLES OF REIMBURSEMENT FOR PROVIDER COSTS UNDER TITLE XVIII OF THE SOCIAL SECURITY ACT AS AMENDED (PUBLIC LAW 89-97)*

Introduction (Reg. Sec. 405.401-405.406)

Under the health insurance program for the aged, the amount paid to any provider of services—i.e., hospital, extended care facility, or home health agency—for the covered services furnished to beneficiaries is required by section 1814(b) and section 1833(a) (2) of the Social Security Act to be the “reasonable cost” of such services.

These principles of reimbursement and the related policies described in this subpart establish the guidelines and procedures to be used by institutional providers, fiscal intermediaries, and the Social Security Administration in determining reasonable cost.

The principles of reimbursement are to be applied on behalf of the program by public and private organizations and agencies acting as fiscal intermediaries in the payment of claims. These organizations and agencies are selected after nomination by groups or associations of hospitals. Extended care facilities and home health agencies may similarly nominate such intermediaries. The fiscal intermediaries are responsible for paying the bills of beneficiaries for covered services received in participating hospitals and other institutions under the medicare program. A provider may deal directly with the Social Security Administration, in which case the same principles are to be used in making payment for services.

In consideration of the wide variations in size and scope of services of providers and regional differences that exist, the principles are flexible on many points. They offer certain alternatives and options designed to fit individual circumstances and to allow time for those providers who do not already collect the statistical and financial data necessary for the reporting of costs to develop the necessary records.

An important role of the fiscal intermediary, in addition to claims processing and payment, and other assigned responsibilities, is to furnish consultative services to providers in the development of accounting and cost-finding procedures which will assure them equitable payment under the program.

Cost Reimbursement; General

In formulating methods for making fair and equitable reimbursement for services rendered beneficiaries of the program, payment is to be made on the basis of current costs of the individual provider, rather than costs of a past period or a fixed negotiated rate. All necessary and proper expenses of an institution in the production of services, including normal standby costs, are recognized. Furthermore, the share of the total institutional cost that is borne by the program is related to the care furnished beneficiaries so that no part of their cost would need to be borne by other patients. Conversely, costs attributable to other patients of the institution are not to be borne by the program. Thus, the application of this approach, with appropriate accounting support, will result in meeting actual costs of services to beneficiaries as such costs vary from institution to institution.

Putting these several points together, certain tests have been evolved for the principles of reimbursement and certain goals have been established that they should be designed to accomplish. In general terms, these are the tests or objectives:

(1) That the methods of reimbursement should result in current payment so that institutions will not be disadvantaged, as they sometimes are under other arrangements, by having to put up money for the purchase of goods and services well before they receive reimbursement.

(2) That, in addition to current payment, there should be retroactive adjustment so that increases in costs are taken fully into account as they actually occurred, not just prospectively.

(3) That there be a division of the allowable costs between the beneficiaries of this program and the other patients of the provider that takes account of the actual use of services by the beneficiaries of this program and that is fair to each provider individually.

(4) That there be sufficient flexibility in the methods of reimbursement to be used, particularly at the beginning of the program, to take account of the great differences in the present state of development of record-keeping.

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(5) That the principles should result in the equitable treatment of both nonprofit organizations and profit-making organizations.

(6) That there should be a recognition of the need of hospitals and other providers to keep pace with growing needs and to make improvements.

As formulated herein, the principles give recognition to such factors as depreciation, interest, bad debts, educational costs, compensation of owners, an allowance for capital funds to secure, preserve, and improve service-rendering capabilities and an allowance for a reasonable return on equity capital of proprietary facilities. With respect to allowable costs some items of inclusion and exclusion are:

(1) An appropriate part of the net cost of approved educational activities will be included.

(2) Costs incurred for research purposes, over and above usual patient care, will not be included.

(3) Grants, gifts, and income from endowments will not be deducted from operating costs unless they are designated by the donor for the payment of specific operating costs.

(4) The value of services provided by nonpaid workers, as members of an organization (including services of members of religious orders) having an agreement with the provider to furnish such services, is includable in the amount that would be paid others for similar work.

(5) Discounts and allowances received on the purchase of goods or services are reductions of the cost to which they relate.

(6) Bad debts growing out of the failure of a beneficiary to pay the deductible, or the coinsurance, will be reimbursed (after bona fide efforts at collection).

(7) Charity and courtesy allowances are not includable, although "fringe benefit" allowances for employees under a formal plan will be includable as part of their compensation.

(8) A reasonable allowance of compensation for the services of owners in profitmaking organizations will be allowed providing their services are actually performed in a necessary function.

In developing these principles of reimbursement for the health insurance program, all of the considerations inherent in allowances for depreciation were studied. The principles, as presented, provide options to meet varied situations. Depreciation will essentially be on an historical cost basis but since many institutions do not have adequate records of old assets, the principles provide an optional allowance in lieu of such depreciation for assets acquired before 1966. For assets acquired after 1965, the historical cost basis must be used. All assets actually in use for production of services for title XVIII beneficiaries will be recognized even though they may have been fully or partially depreciated for other

purposes. Assets financed with public funds may be depreciated. In general, the options for accelerated depreciation will be permitted. Although funding of depreciation is not required, there is an incentive for it since income from funded depreciation is not considered as an offset which must be taken to reduce the interest expense that is allowable as a program cost.

An allowance for costs not specifically recognized is included as an element of allowable cost. The difficulty in measurement of certain costs, lack of adequate data, various uncertainties inherent in the application of any cost formula at the present stage of cost finding capabilities and other consideration have precluded specific recognition of various elements germane to costs of furnishing services. For all providers except proprietary institutions, the allowance in lieu of specific recognition of other costs is 2 percent of the total allowable costs, after exclusion of interest expense and this allowance. For proprietary providers the allowance in lieu of specific recognition of other costs is 1½ percent of total allowable costs after exclusion of interest expense, this allowance, and the return allowed to such providers on their equity capital.

A return on the equity capital of proprietary facilities is an allowable cost in profitmaking organizations. The rate of return may not exceed one and one-half times the average long-term rate of interest on obligations issued for purchase by the Federal Hospital Insurance Trust Fund.

Apportionment of Allowable Costs

Consistent with prevailing practice where third-party organizations pay for health care on a cost basis, reimbursement under the title XVIII health insurance program involves a determination of (1) each provider's allowable costs for producing services, and (2) the share of these costs which is to be borne by title XVIII. The provider's costs are to be determined in accordance with the principles reviewed in the preceding discussion relating to allowable costs; the share to be borne by title XVIII is to be determined in accordance with principles relating to apportionment of cost.

In the study and consideration devoted to the method of apportioning costs, the objective has been to adopt methods for use under title XVIII of the Act that would, to the extent reasonably possible, result in the program's share of a provider's total allowable costs being the same as the program's share of the provider's total services. This result is essential for carrying out the statutory directive that the program's payments to providers should be such that the costs of covered services for beneficiaries would not be passed on to nonbeneficiaries, nor would the cost of services for nonbeneficiaries be borne by the program.

A basic factor bearing upon apportionment of costs is that title XVIII beneficiaries are not a cross section of the total population. Nor will they constitute a cross section of all patients receiving services from most of the providers that participate in the program. Available evidence shows that the use of services by persons age 65 and over differs significantly from other groups. Consequently, the objective sought in the determination of the title XVIII share of a provider's total costs means that the methods used for apportionment must take into account the differences in the amount of services received by patients who are beneficiaries and other patients served by the provider.

The method of cost reimbursements most widely used at the present time by third-party purchasers of in-patient hospital care apportions a provider's total costs among groups served on the basis of the relative number of days of care used. This method, commonly referred to as average per diem cost, does not take into account variations in the amount of service which a day of care may represent and thereby assumes that the patients for whom payment is made on this basis are average in their use of service.

In considering the average per diem method of apportioning cost for use under the program, the difficulty encountered is that the preponderance of presently available evidence strongly indicates that the over-65 patient is not typical from the standpoint of average per diem cost. On the average he stays in the hospital twice as long and therefore the ancillary services that he uses are averaged over the longer period of time, resulting in an average per diem cost for the aged alone, significantly below the average per diem for all patients.

Moreover, the relative use of services by aged patients as compared to other patients differs significantly among institutions. Consequently, considerations of equity among institutions are involved as well as that of effectiveness of the apportionment method under the program in accomplishing the objective of paying each provider fully, but only, for services to beneficiaries.

A further consideration of long-range importance is that the relative use of services by aged and other patients can be expected to change, possibly to a significant extent in future years. The ability of apportionment methods used under the program to reflect such change is an element of flexibility which has been regarded as important in the formulation of the cost reimbursement principles.

An alternative to the relative number of days of care as a basis for apportioning costs is the relative amount of charges billed by the provider for services to patients. The amount of charges is the basis upon which the cost of hospital care is distributed among patients who pay directly for the services they receive. Pay-

ment for services on the basis of charges applies generally under insurance programs where individuals are indemnified for incurred expense, a form of health insurance widely held throughout the Nation. Also, charges to patients are commonly a factor in determining the amount of payment to hospitals under insurance programs providing service benefits, many of which pay "costs or charges, whichever is less" and some of which pay exclusively on the basis of charges. In all of these instances, the provider's own charge structure and method of itemizing services for the purpose of assessing charges is utilized as a measure of the amount of services received and as the basis for allocating responsibility for payment among those receiving the provider's services.

An increasing number of third-party purchasers who pay for services on the basis of cost are developing methods which utilize charges to measure the amount of services for which they have responsibility for payment. In this approach, the amount of charges for such services as a proportion of the provider's total charges to all patients is used to determine the proportion of the provider's total costs for which the third-party purchaser assumes responsibility. The approach is subject to numerous variations. It can be applied to the total of charges for all services combined or it can be applied to components of the provider's activities for which the amount of costs and charges are ascertained through a breakdown of data from provider's accounting records.

For the application of the approach to components, which represent types of services, the breakdown of total costs is accomplished by "cost-finding" techniques under which indirect costs and nonrevenue activities are allocated to revenue producing components for which charges are made as services are rendered.

Methods of Apportionment Under Title XVIII

The principles for reimbursement under title XVIII of the Act establish two basic methods, either of which may be used at the option of a provider, for the determination of the share of allowable costs for which payment is to be made to the provider.

The first alternative is to apply the beneficiaries' share of total charges, on a departmental basis, to total costs for the respective departments. Use of this department-by-department method will involve determination, by cost-finding methods, of the total costs for each of the institution's departments that are revenue-producing; i.e., departments providing services to patients for which charges are made.

The second alternative is a combination method. Under this method, as applied to inpatient care, that part of a provider's total allowable cost which is attributable to routine services (room, board, nursing serv-

ice) is to be apportioned on the basis of the relative number of patient days for beneficiaries and for other patients; i.e., an average cost per diem basis. The residual part of the provider's allowable cost, attributable to nonroutine or ancillary services, is to be apportioned on the basis of the beneficiaries' share of the total charges to patients by the provider for nonroutine or ancillary services. The amounts computed to be the program's share of the two parts of the provider's allowable costs are then combined in determining the amount of reimbursement under the program. Use of the combination method will necessitate cost finding to determine the division of the provider's total allowable costs into the two parts, although it would be less involved than for the first alternative, the department-by-department method.

It is recognized that many hospitals and other providers do not currently employ methods for ascertaining the cost of the services they produce, either by departmental or other groupings of services. Although the use of cost finding has become more extensive among institutions in recent years, for a large number of providers use of the apportionment methods under the program will involve compiling information needed as a basis for breaking down total costs into departmental costs or between routine services and other services, as would need to be done at the end of each accounting year. To avoid an undue burden on providers and to allow ample time for all providers to adopt the cost-finding methods needed for the apportionment methods under the program, a temporary method may be used, at the option of the provider, for accounting periods ending before January 1, 1968. Under this option, a provider may employ the combination method of apportionment by using an estimated percentage obtained from the intermediary as the basis for arriving at a division of total allowable costs between routine and other services. This estimated percentage basis for division of costs will be accepted in lieu of actual cost finding as the basis for the division in the initial reporting period(s) of any provider of service. Furthermore, where there are special factors which make the apportionment methods difficult to apply, the intermediary may approve appropriate adaptations to accomplish the objective of determining the share of the provider's allowable costs which is attributable to services rendered to beneficiaries.

Payments to Providers

The fiscal intermediaries will establish a basis for interim payments to each provider. This may be done by one of several methods. Where an intermediary is already paying the provider on a cost basis, the intermediary can adjust its rate of payment to an estimate of the result under the title XVIII principles of reim-

bursment. Where no organization is paying the provider on a cost basis, the intermediary can obtain the previous year's financial statement from the provider and, by applying the principles of reimbursement, compute or approximate an appropriate rate of payment. The interim payment may be related to the last year's average per diem, or to charges, or to any other ready basis of approximating costs.

At the end of the period, the actual apportionment, based on the cost finding and apportionment methods selected by the provider, will determine the title XVIII reimbursement for the actual services provided to beneficiaries during the period.

Basically, therefore, interim payments to providers will be made for services throughout the year, with final settlement on a retroactive basis at the end of the accounting period. Interim payments will be made as often as possible and in no event less frequently than once a month. The retroactive payments will take fully into account the costs that were actually incurred and settle on an actual, rather than on an estimated basis.

In addition to the basic procedure for payment to a provider following the submission of bills to the intermediary, payment will be made upon request by the provider on a basis designed to reimburse currently as services are furnished to beneficiaries. The amount of such payment will be computed by the intermediary initially on an estimated basis and periodically adjusted to represent the average level of services unreimbursed by the basic payment procedure.

Financial Data and Reports

The principles of cost reimbursement will require that providers maintain sufficient financial records and statistical data for proper determination of costs payable under the program. Standardized definitions, accounting, statistics, and reporting practices which are widely accepted in the hospital and related fields are followed. Changes in these practices and systems will not be required in order to determine costs payable under the principles of reimbursement. Essentially the methods of determining costs payable under title XVIII involve making use of data available from the institution's basic accounts, as usually maintained, to arrive at equitable and proper payment for services to beneficiaries.

Costs reports will be required from providers on an annual basis with reporting periods based on the provider's accounting year. In the interpretation and application of the principles of reimbursement, the fiscal intermediaries will be an important source of consultative assistance to providers and will be available to deal with questions and problems on a day-to-day basis.

PRINCIPLES FOR SPECIFIC REIMBURSABLE COSTS*

1-1 Depreciation

1-1A Allowance for Depreciation Based on Asset Costs (Reg. Sec. 405.415)

Principle

An appropriate allowance for depreciation on buildings and equipment is an allowable cost. The depreciation must be:

(1) Identifiable and recorded in the provider's accounting records;

(2) Based on the historical cost of the asset or fair market value at the time of donation in the case of donated assets; and

(3) Prorated over the estimated useful life of the asset using the straight-line method or accelerated depreciation under the declining balance or sum-of-the-years' digits methods.

Definitions

(1) Historical costs. Historical cost is the cost incurred by the present owner in acquiring the asset.

(2) Fair market value. Fair market value is the price that the asset would bring by bona fide bargaining between well-informed buyers and sellers at the date of acquisition. Usually the fair market price will be the price at which bona fide sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition.

(3) The straight-line method. Under the straight-line method of depreciation, the cost or other basis (e.g. fair market value in the case of donated assets) of the asset, less its estimated salvage value, if any, is determined first. Then this amount is distributed in equal amounts over the period of the estimated useful life of the asset.

(4) Declining balance method. Under the declining balance method, the annual depreciation allowance is computed by multiplying the undepreciated balance of the asset each year by a uniform rate up to double the straight-line rate.

(5) Sum-of-the-years' digits method. Under the sum-of-the-years' digits method, the annual depreciation allowance is computed by multiplying the depreciable cost basis (cost less salvage value) by a constantly decreasing fraction. The numerator of the fraction is

represented by the remaining years of useful life of the asset at the beginning of each year, and the denominator is always represented by the sum of the years' digits of useful life at the time of acquisition.

Recording of depreciation

Appropriate recording of depreciation encompasses the identification of the depreciable assets in use, the assets' historical costs, the method of depreciation, estimated useful life, and the assets' accumulated depreciation. The Chart of Accounts published by the American Hospital Association and publications of the Internal Revenue Service are to be used as guides for the estimation of the useful life of assets.

Depreciation methods

(1) Proration of the cost of an asset over its useful life will be allowed on the straight-line, the declining balance, or the sum-of-the-years' digits methods. The provider may choose to use one of the methods on a single asset or group of assets and another method on others. In applying the declining balance or sum-of-the-years' digits method to an asset that is not new, the undepreciated balance of the asset is to be treated as the cost of a new asset in computing the depreciation.

(2) A provider may change from the straight-line method to an accelerated method or vice versa upon advance approval from the intermediary on a prospective basis with the request being made before the end of the first month of the prospective reporting period. Only one such change with respect to a particular asset may be made by a provider.

Funding of depreciation

Although funding of depreciation is not required, it is strongly recommended that providers use this mechanism as a means of conserving funds for replacement of depreciable assets, and coordinate their planning of capital expenditures with areawide planning activities of community and State agencies. As an incentive for funding, investment income on funded depreciation will

*AUTHORITY: 20 CFR 405, §§ 405.401-405.454 issued secs. 1102, 1814(b), 1861(v), and 1871, 49 Stat. 647, as amended, 79 Stat. 296, 79 Stat. 322, 79 Stat. 331; 42 U.S.C. 1302, 1395 et seq.

not be treated as a reduction of allowable interest expense.

Gains and losses on disposal of assets

Gains and losses realized from the disposal of depreciable assets are to be included in the determination of allowable cost. The extent to which such gains and losses are includable is to be calculated on a proration basis recognizing the amount of depreciation charged under the program in relation to the amount of depreciation, if any, charged or assumed in a period prior to the provider's participation in the program.

1-1B Optional Allowance for Depreciation Based on a Percentage of Operating Costs (Reg. Sec. 405.416)

Principle

With respect to all assets acquired before 1966, the provider, at its option, may choose an allowance for depreciation based on a percentage of operating costs. The operating costs to be used are the lower of the provider's 1965 operating costs or the provider's current year's allowable costs. The percent to be applied is 5 percent starting with the year 1966-67, with such percentage being uniformly reduced by one-half percent each succeeding year. The allowance based on operating costs is in addition to regular depreciation on assets acquired after 1965; however, when the optional allowance is selected, the combined amount of such allowance on pre-1966 assets and the straight-line depreciation on assets acquired or rented after 1965 may not exceed 6 percent of the provider's allowable cost for the current year.

Definitions

(1) *Operating costs.* Operating costs are the total costs incurred by the provider in operating the institution or facility.

(2) *Allowable costs.* Allowable costs are the costs of a provider which are includable under the principles for cost reimbursement; by the application of apportionment methods to the total amount of such allowable costs, the share of a provider's total cost which is attributable to covered services for beneficiaries is determined.

Application

Where a provider has inadequate historical costs records for pre-1966 depreciable assets, the provider may elect to receive an allowance for depreciation on such assets based on a percentage of operating costs. The optional allowance for depreciation for such assets may be used, however, whether or not a provider has

Establishment of cost basis on purchase of facility as ongoing operation

In establishing the cost basis for a facility purchased as an ongoing operation after July 1, 1966, the price paid by the purchaser shall be the cost basis where the purchaser can demonstrate that the sale was a bona fide sale and the price did not exceed the fair market value of the facility at the time of sale. The cost basis for depreciation of depreciable assets shall not exceed the fair market value of those assets at the time of sale. If the sale is not demonstrated to be bona fide, the seller's cost basis shall be the cost basis to the purchaser.

records of the cost of pre-1966 depreciable assets currently in use.

Allowance based on a percentage of operating costs

(1) The allowance for depreciation based on a percentage of operating costs is to be computed by applying a specified percentage to a base amount equal to the provider's 1965 total operating costs, without adjustments to these principles or the current year's allowable operating costs, whichever is lower. The percentage to be applied would be five for 1966-67, four and one-half for 1967-68, and would so continue to decline annually by equal amounts to become zero in 1976-77.

(2) When used as a base for determining the optional allowance for depreciation, neither the 1965 operating costs nor the current year's allowable costs are to include any actual depreciation, estimated depreciation on rented depreciable-type assets, allowance in lieu of specific recognition of other costs, or return on equity capital. Such exclusions are to be made only for the purpose of computing the allowance for depreciation based on operating costs. For other purposes, the excluded amounts are recognized in determining allowable costs and for computing the costs for services rendered to the program beneficiaries during the reporting period.

Change to actual depreciation

(1) A provider that elects this allowance may at any time before 1976 change to actual depreciation on all pre-1966 depreciable assets. In such case, this option is eliminated and the provider can no longer elect to receive an allowance for depreciation based on a percentage of operating costs.

(2) Where the provider desires to change to actual depreciation but either has no historical cost records or has incomplete records, the determination of historical cost could be made through appropriate means involv-

ing expert consultation with the determination being subject to review and approval by the intermediary.

Determination of optional allowance based on percentage of operating costs illustrated.

The following illustrates how the provider would determine the optional allowance for depreciation based on operating costs.

Example No. 1—The provider keeps its records on a calendar year basis. The current year's actual allowable cost and the actual operating cost for 1965 do not include any actual depreciation or rentals on depreciable-type assets. The current year's allowable cost also does not include any allowance in lieu of specific recognition of other costs or return on equity capital.

Year 1966

Current year's allowable cost.....	\$1,100,000
Operating cost for 1965 ¹	\$1,000,000
Percent for determining the allowance.....	5
Allowance	\$50,000

¹ 1965 operating cost was used in computing the allowance for depreciation based on a percentage of operating costs because it was lower than 1966 allowable cost.

Year 1967

Current year's allowable cost.....	\$1,200,000
Operating cost for 1965 ¹	\$1,000,000
Percent for determining the allowance ²	5
Allowance	\$50,000

¹ 1965 operating cost was used in computing the allowance for depreciation based on a percentage of operating costs because it was lower than 1967 allowable cost.

² Since the reporting period began during the year 1966-67 (July 1, 1966-June 30, 1967) 5 percent is the percentage to be used.

Year 1968

Operating cost for 1965.....	\$1,000,000
Current year's allowable cost ¹	\$900,000
Percent for determining the allowance ²	4½
Allowance	\$40,500

¹ The current year's allowable cost was used in computing the allowance for depreciation based on percentage of operating costs because it was lower than 1965 operating cost.

² Since the reporting period began during the year 1967-68 (July 1, 1967-June 30, 1968) 4½ percent is the percentage to be used.

Example No. 2—When the provider pays rent for depreciable-type assets rented prior to 1966, the estimated depreciation on such assets must be deducted from the allowance. The following illustration demonstrates how the allowance is determined.

The provider keeps its records on a calendar year

basis. The current year's actual allowable cost and the actual operating cost for 1965 did not include any actual depreciation, allowance in lieu of specific recognition of other costs, or return on equity capital. However, such costs have been adjusted to exclude estimated depreciation on rented depreciable-type assets.

Year 1966

Adjusted current year's allowable cost.....	\$1,100,000
Adjusted operating cost for 1965 ¹	\$1,000,000
Percent for determining the allowance.....	5
Allowance	\$50,000
Less estimated depreciation for depreciable-type assets rented prior to 1966 on which rental is paid in 1966.....	3,000
Adjusted allowance.....	\$47,000

¹ 1965 operating cost was used in computing the allowance for depreciation based on a percentage of operating costs because it was lower than 1966 allowable cost.

Limitation on depreciation where optional allowance is used.

This optional allowance only is subject to a limitation based on the provider's total allowable operating cost for the current year. To determine this limitation, compute the sum of the actual depreciation claimed, the allowance based on a percentage of operating costs and the estimated straight-line depreciation on depreciable-type assets rented after 1965. If this sum exceeds 6 percent of the provider's current year's allowable cost (exclusive of any actual depreciation claimed, estimated depreciation on rented depreciable-type assets, allowance in lieu of specific recognition of other costs, and return on equity capital), the allowance for depreciation based on a percentage of operating costs will be reduced by the amount of excess. In applying this limitation, if the actual depreciation claimed is on an accelerated basis it must be converted to a straight-line basis only for use in calculating this limitation. It is presumed that pre-1966 assets will not be retired at a greater than normal rate, and the limitation of 6 percent, as it affects the availability of the allowance, is designed as a safeguard where the presumption is not borne out. Where the provider does not elect to use the optional allowance, the combined allowance for depreciation based on costs of pre-1966 assets and those subsequently acquired is not subject to the 6-percent limitation.

Example No. 1—The following illustration demonstrates how this limitation would be determined.

Year 1966

The provider keeps its records on a calendar year basis. The current year's actual allowable cost and the actual operating cost for 1965 have been adjusted to exclude actual depreciation,

the estimated depreciation on rented depreciable-type assets, allowance in lieu of specific recognition of other costs, and return on equity capital.

Adjusted operating cost for 1965.....	\$1,000,000
Percent for determining the allowance.....	5
In 1966 assets were acquired which produce a straight-line depreciation of.....	\$18,000
Estimated depreciation on assets rented in 1966....	\$2,000
Adjusted allowable operating cost for 1966.....	\$1,100,000

CALCULATION OF ALLOWANCE FOR DEPRECIATION BASED ON A PERCENTAGE OF OPERATING COSTS

Gross allowance:	
5% times adjusted 1965 operating costs (\$1,000,000)	\$50,000
Estimated depreciation on assets rented in 1966....	2,000
Straight-line depreciation on post-1965 assets.....	18,000
Total	\$70,000
6% of adjusted 1966 allowable operating cost.....	66,000
Deduction in allowance.....	\$4,000

CALCULATION OF ALLOWANCE FOR DEPRECIATION BASED ON A PERCENTAGE OF OPERATING COSTS—Continued

Allowance	\$50,000
Reduction	4,000
Adjusted allowance.....	\$46,000
Total depreciation allowance for 1966 (\$18,000 actual depreciation plus \$46,000 allowance based on operating cost)	\$64,000

Assume in this illustration that the provider had elected to use the declining balance method in computing its allowable depreciation and the rental expense for depreciable-type assets was \$3,500. In that case, it would include in its 1966 allowable cost not only the \$46,000 allowance based on operating costs but also \$36,000 (in this instance $2 \times$ straight-line rate is used) in actual depreciation and the rental expense of \$3,500—or a total of \$85,500 covering all its depreciable assets.

1-1C Allowance for Depreciation on Fully Depreciated or Partially Depreciated Assets (Reg. Sec. 405.417)

Principle

Depreciation on assets being used by a provider at the time it enters into the title XVIII program is allowed; this applies even though such assets may be fully or partially depreciated on the provider's books.

Application

Depreciation is allowable on assets being used at the time the provider enters into the program. This applies even though such assets may be fully depreciated on the provider's books or fully depreciated with respect to other third-party payers. So long as an asset is being used, its useful life is considered not to have ended, and consequently the asset is subject to depreciation based upon a revised estimate of the asset's useful life as determined by the provider and approved by the intermediary. Correction of prior years' depreciation to reflect revision of estimated useful life should be made in the first year of participation in the program unless the provider has used the optional method principle 1-1B (Reg. Sec. 405.416), in which case the correction should be made at the time of discontinuing

the use of that method. When an asset has become fully depreciated under title XVIII, further depreciation would not be appropriate or allowable, even though the asset may continue in use. For example, if a 50-year-old building is in use at the time the provider enters into the program, depreciation is allowable on the building even though it has been fully depreciated on the provider's books. Assuming that a reasonable estimate of the asset's continued life is 20 years (70 years from the date of acquisition), the provider may claim depreciation over the next 20 years—if the asset is in use that long—or a total depreciation of as much as twenty-seventieths of the asset's historical cost. If the asset is disposed of before the expiration of its estimated useful life, the depreciation would be adjusted to the actual useful life. Likewise, a provider may not have fully depreciated other assets it is using and finds that it has incorrectly estimated the useful lives of those assets. In such cases, the provider may use the corrected useful lives in determining the amount of depreciation, provided such corrections have been approved by the intermediary.

**1-1D Allowance for Depreciation on Assets Financed With Federal or Public Funds
(Reg. Sec. 405.418)**

Principle

Depreciation is allowed on assets financed with Hill-Burton or other Federal or public funds.

Application

Like other assets (including other donated depreciable assets), assets financed with Hill-Burton or other Federal or public funds become a part of the provider institution's plant and equipment to be used in rendering services. It is the function of payment of depreciation to provide funds which make it possible to maintain the assets and preserve the capital employed in

the production of services. Therefore, irrespective of the source of financing of an asset, if it is used in the providing of services for beneficiaries of the program, payment for depreciation of the asset is, in fact, a cost of the production of those services. Moreover, recognition of this cost is necessary to maintain productive capacity for the future. An incentive for funding of depreciation is provided in these principles by the provision that investment income on funded depreciation is not treated as a reduction of allowable interest expense under principle 1-2 (Reg. Sec. 405.419) which follows.

1-2 Interest Expense (Reg. Sec. 405.419)

Principle

Necessary and proper interest on both current and capital indebtedness is an allowable cost.

Definitions

(1) *Interest.* Interest is the cost incurred for the use of borrowed funds. Interest on current indebtedness is the cost incurred for funds borrowed for a relatively short term. This is usually for such purposes as working capital for normal operating expenses. Interest on capital indebtedness is the cost incurred for funds borrowed for capital purposes, such as acquisition of facilities and equipment, and capital improvements. Generally, loans for capital purposes are long-term loans.

(2) *Necessary.* Necessary requires that the interest:

(i) Be incurred on a loan made to satisfy a financial need of the provider. Loans which result in excess funds or investments would not be considered necessary.

(ii) Be incurred on a loan made for a purpose reasonably related to patient care.

(iii) Be reduced by investment income except where such income is from gifts and grants, whether restricted or unrestricted, and which are held separate and not commingled with other funds. Income from funded depreciation or provider's qualified pension fund is not used to reduce interest expense.

(3) *Proper.* Proper requires that interest:

(i) Be incurred at a rate not in excess of what a prudent borrower would have had to pay in the money market existing at the time the loan was made.

(ii) Be paid to a lender not related through control or ownership, or personal relationship to the borrowing organization. However, interest is allowable if paid on loans from the provider's donor-restricted funds, the funded depreciation account, or provider's qualified pension fund.

Borrower-lender relationship

(1) To be allowable, interest expense must be incurred on indebtedness established with lenders or lending organizations not related through control, ownership, or personal relationship to the borrower. Presence of any of these factors could affect the "bargaining" process that usually accompanies the making of a loan, and could thus be suggestive of an agreement on higher rates of interest or of unnecessary

loans. Loans should be made under terms and conditions that a prudent borrower would make in arms-length transactions with lending institutions. The intent of this provision is to assure that loans are legitimate and needed, and that the interest rate is reasonable. Thus, interest paid by the provider to partners, stockholders, or related organizations of the provider would not be allowable. Where the owner uses his own funds in a business, it is reasonable to treat the funds as invested funds or capital, rather than borrowed funds. Therefore, where interest on loans by partners, stockholders, or related organizations is disallowed as a cost solely because of the relationship factor, the principal of such loans shall be treated as invested funds in the computation of the provider's equity capital under principle 1-12 (Reg. Sec. 405.429).

(2) Exceptions to the general rule regarding interest on loans from controlled sources of funds are made in the following circumstances. Interest on loans to providers by partners, stockholders, or related organizations made prior to July 1, 1966, is allowable as cost, provided that the terms and conditions of payment of such loans have been maintained in effect without modification subsequent to July 1, 1966. Where the general fund of a provider "borrows" from a donor-restricted fund and pays interest to the restricted fund, this interest expense is an allowable cost. The same treatment is accorded interest paid by the general fund on money "borrowed" from the funded depreciation account of the provider or from the provider's qualified pension fund. In addition, if a provider operated by members of a religious order borrows from the order, interest paid to the order is an allowable cost.

(3) Where funded depreciation is used for purposes other than improvement, replacement, or expansion of facilities or equipment related to patient care, allowable interest expense is reduced to adjust for offsets not made in prior years for earnings on funded depreciation. A similar treatment will be accorded deposits in the provider's qualified pension fund where such deposits are used for other than the purpose for which the fund was established.

(4) Allowable interest expense on current indebtedness of a provider will be adjusted to reflect the extent to which working capital needs which are attributable to covered services for beneficiaries have been met by payments to the provider designed to reimburse currently as services are furnished to beneficiaries.

1-3 Bad Debts, Charity, and Courtesy Allowances (Reg. Sec. 405.420)

Principle

Bad debts, charity, and courtesy allowances are deductions from revenue and are not to be included in allowable cost; however, bad debts attributable to the deductibles and coinsurance amounts are reimbursable under the program.

Definitions

(1) *Bad debts.* Bad debts are amounts considered to be uncollectible from accounts and notes receivable which were created or acquired in providing services. "Accounts receivable" and "notes receivable" are designations for claims arising from the rendering of services, and are collectible in money in the relatively near future.

(2) *Charity allowances.* Charity allowances are reductions in charges made by the provider of services because of the indigence or medical indigence of the patient.

(3) *Courtesy allowances.* Courtesy allowances indicate a reduction in charges in the form of an allowance to physicians, clergy, members of religious orders, and others as approved by the governing body of the provider, for services received from the provider. Employee fringe benefits, such as hospitalization and personnel health programs, are not considered to be courtesy allowances.

Normal accounting treatment: reduction in revenue

Bad debts, charity, and courtesy allowances represent reductions in revenue. The failure to collect charges for services rendered does not add to the cost of providing the services. Such costs have already been incurred in the production of the services.

Requirements of title XVIII

Under title XVIII of the Act costs of covered services furnished beneficiaries are not to be borne by individuals not covered by the health insurance program, and conversely, costs of services provided for other than beneficiaries are not to be borne by the health insurance program. Uncollected revenue related to serv-

ices rendered to beneficiaries of the program generally means the provider has not recovered the cost of services covered by that revenue. The failure of beneficiaries to pay the deductible and coinsurance amounts can result in the related costs of covered services being borne by other than beneficiaries of title XVIII. To assure that such covered service costs are not borne by others, the costs attributable to the deductible and coinsurance amounts which remain unpaid are added to the title XVIII share of allowable costs. Bad debts arising from other sources are not allowable costs.

Criteria for allowable bad debt

A bad debt must meet the following criteria to be allowable:

(1) The debt must be related to covered services and derived from deductible and coinsurance amounts.

(2) The provider must be able to establish that reasonable collection efforts were made.

(3) The debt was actually uncollectible when claimed as worthless.

(4) Sound business judgment established that there was no likelihood of recovery at any time in the future.

Charging of bad debts and bad debt recoveries

The amounts uncollectible from specific beneficiaries are to be charged off as bad debts in the accounting period in which the accounts are deemed to be worthless. In some cases an amount previously written off as a bad debt and allocated to the program may be recovered in a subsequent accounting period; in such cases the income therefrom must be used to reduce the cost of beneficiary services for the period in which the collection is made.

Charity allowances

Charity allowances have no relationship to beneficiaries of the health insurance program and are not allowable costs. The cost to the provider of employee fringe-benefit programs is an allowable element of reimbursement.

1-4 Cost of Educational Activities (Reg. Sec. 405.421)

Principle

An appropriate part of the net cost of approved educational activities is an allowable cost.

Definitions

(1) *Approved educational activities.* Approved educational activities means formally organized or planned programs of study usually engaged in by providers in order to enhance the quality of patient care in an institution. These activities must be licensed where required by State law. Where licensing is not required, the institution must receive approval from the recognized national professional organization for the particular activity.

(2) *Net cost.* The net cost means the cost of approved educational activities (including stipends of trainees, compensation of teachers, and other costs), less any reimbursements from grants, tuition, and specific donations.

(3) *Appropriate part.* Appropriate part means the net cost of the activity apportioned in accordance with the methods set forth in these principles.

Educational activities

Many providers engage in educational activities including training programs for nurses, medical students, interns and residents, and various paramedical specialties. These programs contribute to the quality of patient care within an institution and are necessary to meet the community's needs for medical and paramedical personnel. It is recognized that the costs of such educational activities should be borne by the community. However, many communities have not assumed responsibility for financing these programs and it is necessary that support be provided by those purchasing health care. Until communities undertake to bear these costs, the program will participate appropriately in the support of these activities. Although the intent of the program is to share in the support of educational activities customarily or traditionally carried on by providers in conjunction with their operations, it is not intended that this program should participate in increased costs resulting from redistribution of costs from educational institutions or units to patient care institutions or units.

"Orientation" and "on-the-job training"

The costs of "orientation" and "on-the-job training" are not within the scope of this principle but are recognized as normal operating costs in accordance with principles relating thereto.

Approved programs

In addition to approved medical, osteopathic, and dental internships and residency programs, recognized professional and paramedical educational and training programs now being conducted by provider institutions, and their approving bodies, include the following:

Program	Approving bodies
(1) Cytotechnology.....	Council on Medical Education of the American Medical Association in collaboration with the Board of Schools of Medical Technology, American Society of Clinical Pathologists.
(2) Dietetic internships....	The American Dietetic Association.
(3) Hospital administration residencies.	Members of the Association of University Programs in Hospital Administration.
(4) Inhalation therapy.....	Council on Medical Education of the American Medical Association in collaboration with the Board of Schools of Inhalation Therapy.
(5) Medical records.....	Council on Medical Education of the American Medical Association in collaboration with the Committee on Education and Registration of the American Association of Medical Record Librarians.
(6) Medical technology....	Council on Medical Education of the American Medical Association in collaboration with the Board of Schools of Medical Technology, American Society of Clinical Pathologists.
(7) Nurse anesthetists.....	The American Association of Nurse Anesthetists.
(8) Professional nursing...	Approved by the respective State approving authorities. Reported for the United States by the National League for Nursing.
(9) Practical nursing.....	Approved by the respective State approving authorities. Reported for the United States by the National League for Nursing.

*Program**Approving bodies*

- (10) Occupational therapy... Council on Medical Education of the American Medical Association in collaboration with the Council on Education of the American Occupational Therapy Association.
- (11) Pharmacy residencies... American Society of Hospital Pharmacists.
- (12) Physical therapy..... Council on Medical Education of the American Medical Association in collaboration with the American Physical Therapy Association.
- (13) X-ray technology..... Council on Medical Education of the American Medical Association in collaboration with the American College of Radiology.

*Program**Approving bodies*

sociation in collaboration with the American College of Radiology.

Other educational programs

There may also be other educational programs not included in the foregoing in which a provider institution is engaged. Appropriate consideration will be given by the intermediary and the Social Security Administration to the costs incurred for those activities that come within the purview of the principle when determining the allowable costs for apportionment under the health insurance program.

1-5 Research Costs (Reg. Sec. 405.422)

Principle

Costs incurred for research purposes, over and above usual patient care, are not includible as allowable costs.

Application

(1) There are numerous sources of financing for health-related research activities. Funds for this purpose are provided under many Federal programs and by other tax-supported agencies. Also, many foundations, voluntary health agencies, and other private organizations, as well as individuals, sponsor or contribute to the support of medical and related research. Funds available from such sources are generally ample to meet

basic medical and hospital research needs. A further consideration is that quality review should be assured as a condition of governmental support for research. Provisions for such review would introduce special difficulties in the health insurance program.

(2) Where research is conducted in conjunction with and as a part of the care of patients, the costs of usual patient care are allowable to the extent that such costs are not met by funds provided for the research. Under this principle, however, studies, analyses, surveys, and related activities to serve the provider's administrative and program needs, are not excluded as allowable costs in the determination of reimbursement under title XVIII of the Act.

1-6 Grants, Gifts, and Income From Endowments (Reg. Sec. 405.423)

Principle

Unrestricted grants, gifts, and income from endowments should not be deducted from operating costs in computing reimbursable cost. Grants, gifts, or endowment income designated by a donor for paying specific operating costs should be deducted from the particular operating cost or group of costs.

Definitions

(1) *Unrestricted grants, gifts, income from endowment.* Unrestricted grants, gifts, and income from endowments are funds, cash or otherwise, given to a provider without restriction by the donor as to their use.

(2) *Designated or restricted grants, gifts, and income from endowments.* Designated or restricted grants, gifts, and income from endowments are funds, cash or otherwise, which must be used only for the specific purpose designated by the donor. This does not refer to unrestricted grants, gifts, or income from

endowments which have been restricted for a specific purpose by the provider.

Application

(1) Unrestricted funds, cash or otherwise, are generally the property of the provider to be used in any manner its management deems appropriate and should not be deducted from operating costs. It would be inequitable to require providers to use the unrestricted funds to reduce the payments for care. The use of these funds is generally a means of recovering costs which are not otherwise recoverable.

(2) Donor-restricted funds which are designated for paying certain hospital operating expenses should apply and serve to reduce these costs or group of costs and benefit all patients who use services covered by the donation. If such costs are not reduced, the provider would secure reimbursement for the same expense twice; it would be reimbursed through the donor-restricted contributions as well as from patients and third-party payers including the title XVIII health insurance program.

1-7 Value of Services of Nonpaid Workers (Reg. Sec. 405.424)

Principle

The value of services in positions customarily held by full-time employees performed on a regular, scheduled basis by individuals as nonpaid members of organizations under arrangements between such organizations and a provider for the performance of such services without direct remuneration from the provider to such individuals is allowable as an operating expense for the determination of allowable cost subject to the limitation contained in this section. The amounts allowed are not to exceed those paid others for similar work. Such amounts must be identifiable in the records of the institutions as a legal obligation for operating expenses.

Limitations; services of nonpaid workers

The services must be performed on a regular, scheduled basis in positions customarily held by full-time employees and necessary to enable the provider to carry out the functions of normal patient care and operation of the institution. The value of services of a type for which providers generally do not remunerate individ-

uals performing such services is not allowable as a reimbursable cost under the title XVIII health insurance program. For example, donated services of individuals in distributing books and magazines to patients, or in serving in a provider canteen or cafeteria or in a provider gift shop, would not be reimbursable.

Application

The following illustrates how a provider would determine an amount to be allowed under this principle: The prevailing salary for a lay nurse working in Hospital A is \$5,000 for the year. The lay nurse receives no maintenance or special perquisites. A sister working as a nurse engaged in the same activities in the same hospital receives maintenance and special perquisites which cost the hospital \$2,000 and are included in the hospital's allowable operating costs. The hospital would then include in its records an additional \$3,000 to bring the value of the services rendered to \$5,000. The amount of \$3,000 would be allowable where the provider assumes obligation for the expense under a written agreement with the sisterhood or other religious order covering payment by the provider for the services.

1-8 Purchase Discounts and Allowances, and Refunds of Expenses (Reg. Sec. 405-425)

Principle

Discounts and allowances received on purchases of goods or services are reductions of the costs to which they relate. Similarly, refunds of previous expense payments are reductions of the related expense.

Definitions

(1) *Discounts.* Discounts, in general, are reductions granted for the settlement of debts.

(2) *Allowances.* Allowances are deductions granted for damage, delay, shortage, imperfection, or other causes, excluding discounts and returns.

(3) *Refunds.* Refunds are amounts paid back or a credit allowed on account of an overcollection.

Normal accounting treatment: reduction of costs

All discounts, allowances, and refunds of expenses are reductions in the cost of goods or services purchased and are not income. When they are received in the same accounting period in which the purchases were made or expenses were incurred, they will reduce the purchases or expenses of that period. However, when they are received in a later accounting period, they will reduce the comparable purchases or expenses in the period in which they are received.

Application

(1) Purchase discounts have been classified as cash, trade, or quantity discounts. Cash discounts are reductions granted for the settlement of debts before they are due. Trade discounts are reductions from list prices granted to a class of customers before consideration of credit terms. Quantity discounts are reductions from list prices granted because of the size of individual or aggregate purchase transactions. Whatever the classification of purchase discounts, like treatment in reducing allowable costs is required. In the past, purchase discounts were considered as financial management income. However, modern accounting theory holds that income is not derived from a purchase but rather from a sale or an exchange and that purchase discounts are reductions in the cost of whatever was purchased. The true cost of the goods or services is the net amount actually paid for them. Treating purchase discounts as income would result in an overstatement of costs to the extent of the discount.

(2) As with discounts, allowances, and rebates received from purchases of goods or services and refunds of previous expense payments are clearly reductions in costs and must be reflected in the determination of allowable costs. This treatment is equitable and is in accord with that generally followed by other governmental programs and third-party payment organizations paying on the basis of cost.

1-9 Compensation of Owners (Reg. Sec. 405.426)

Principle

A reasonable allowance of compensation for services of owners is an allowable cost, provided the services are actually performed in a necessary function.

Definitions

(1) *Compensation.* Compensation means the total benefit received by the owner for the services he renders to the institution. It includes:

(i) Salary amounts paid for managerial, administrative, professional, and other services.

(ii) Amounts paid by the institution for the personal benefit of the proprietor.

(iii) The cost of assets and services which the proprietor receives from the institution.

(iv) Deferred compensation.

(2) *Reasonableness.* Reasonableness requires that the compensation allowance:

(i) Be such an amount as would ordinarily be paid for comparable services by comparable institutions.

(ii) Depend upon the facts and circumstances of each case.

(3) *Necessary.* Necessary requires that the function:

(i) Be such that had the owner not rendered the

services, the institution would have had to employ another person to perform the services.

(ii) Be pertinent to the operation and sound conduct of the institution.

Application

(1) Owners of provider organizations often render services as managers, administrators, or in other capacities. In such cases, it is equitable that reasonable compensation for the services rendered be an allowable cost. To do otherwise would disadvantage such owners in comparison with corporate providers or providers employing persons to perform similar services.

(2) Ordinarily, compensation paid to proprietors is a distribution of profits. However, where a proprietor renders necessary services for the institution, the institution is in effect employing his services, and a reasonable compensation for these services is an allowable cost. In corporate providers, the salaries of owners who are also employees are subject to the same requirements of reasonableness. Where the services are rendered on less than a full-time basis, the allowable compensation should reflect an amount proportionate to a full-time basis. Reasonableness of compensation may be determined by reference to, or in comparison with, compensation paid for comparable services and responsibilities in comparable institutions; or it may be determined by other appropriate means.

1-10 Cost to Related Organizations (Reg. Sec. 405.427)

Principle

Costs applicable to services, facilities, and supplies furnished to the provider by organizations related to the provider by common ownership or control are includable in the allowable cost of the provider at the cost to the related organization. However, such cost must not exceed the price of comparable services, facilities, or supplies that could be purchased elsewhere.

Definitions

(1) *Related to provider.* Related to the provider means that the provider to a significant extent is associated or affiliated with or has control of or is controlled by the organization furnishing the services, facilities, or supplies.

(2) *Common ownership.* Common ownership exists when an individual or individuals possess significant ownership or equity in the provider and the institution or organization serving the provider.

(3) *Control.* Control exists where an individual or an organization has the power, directly or indirectly, significantly to influence or direct the actions or policies of an organization or institution.

Application

(1) Individuals and organizations associate with others for various reasons and by various means. Some deem it appropriate to do so to assure a steady flow of supplies or services, to reduce competition, to gain a tax advantage, to extend influence, and for other reasons. These goals may be accomplished by means of ownership or control, by financial assistance, by management assistance, and other ways.

(2) Where the provider obtains items of services, facilities, or supplies from an organization, even though it is a separate legal entity, and the organization is

owned or controlled by the owner(s) of the provider, in effect the items are obtained from itself. An example would be a corporation building a hospital or a nursing home and then leasing it to another corporation controlled by the owner. Therefore, reimbursable cost should include the costs for these items at the cost to the supplying organization. However, if the price in the open market for comparable services, facilities, or supplies is lower than the cost to the supplier, the allowable cost to the provider shall not exceed the market price.

Exception

An exception is provided to this general principle if the provider demonstrates by convincing evidence to the satisfaction of the fiscal intermediary (or, where the provider has not nominated a fiscal intermediary, the Social Security Administration), that the supplying organization is a bona fide separate organization; that a substantial part of its business activity of the type carried on with the provider is transacted with others than the provider and organizations related to the supplier by common ownership or control and there is an open, competitive market for the type of services, facilities, or supplies furnished by the organization; that the services, facilities, or supplies are those which commonly are obtained by institutions such as the provider from other organizations and are not a basic element of patient care ordinarily furnished directly to patients by such institutions; and that the charge to the provider is in line with the charge for such services, facilities, or supplies in the open market and no more than the charge made under comparable circumstances to others by the organization for such services, facilities, or supplies. In such cases, the charge by the supplier to the provider for such services, facilities, or supplies shall be allowable as cost.

1-11 Allowance in Lieu of Specific Recognition of Other Costs (Reg. Sec. 405.428)

Principle

In lieu of specific recognition of other costs in providing and improving services, an allowance amounting to 2 percent of allowable costs (with the exception of interest expense and the allowance under this principle) is includible as an element of reasonable cost of services except that, for proprietary providers, the allowance shall be 1½ percent of allowable costs (with the exception of interest expense, the allowance under this principle and the return allowed on equity capital).

Application

Difficulty in measurement, lack of adequate data and other considerations have precluded specific recognition

of various elements which are germane to costs of services for beneficiaries. Moreover, although the methods to be utilized by providers for determining the actual cost of services provided to beneficiaries are the best available, there is some lack of precision in methods for determining costs at the present stage of development of cost finding which represents a contingency for which recognition is appropriate. It is the established practice of a significant number of large third-party purchasers to include in payment for costs of services a factor in the form of an allowance to cover various elements not specifically recognized or not precisely measured. The reduction in the allowance for proprietary providers is made because a return on equity capital is specifically recognized as a cost for proprietary providers under principle 1-12 (Reg. Sec. 405.429).

1-12 Return on Equity Capital of Proprietary Providers (Reg. Sec. 405.429)

Principle

An allowance of a reasonable return on equity capital invested and used in the provision of patient care is allowable as an element of the reasonable cost of covered services furnished to beneficiaries by proprietary providers. The amount allowable on an annual basis is determined by applying to the provider's equity capital a percentage equal to one and one-half times the average of the rates of interest on special issues of public debt obligations issued to the Federal Hospital Insurance Trust Fund for each of the months during the provider's reporting period or portion thereof covered under the program.

Application

Proprietary providers generally do not receive public contributions and assistance of Federal and other governmental programs such as Hill-Burton in financing capital expenditures. Proprietary institutions historically have financed capital expenditures through funds invested by owners in the expectation of earning a return. A return on investment, therefore, is needed to avoid withdrawal of capital and to attract additional capital needed for expansion. For purposes of computing the allowable return, the provider's equity capital means: (1) The provider's investment in plant, property, and equipment related to patient care (net of depreciation) and funds deposited by a provider who leases plant, property, or equipment related to patient care and is required by the terms of the lease to deposit such funds (net of noncurrent debt related to such in-

vestment or deposited funds), and (2) net working capital maintained for necessary and proper operation of patient care activities (excluding the amount of any current payment made pursuant to principle 2-4 (Reg. Sec. 405.454)). However, debt representing loans from partners, stockholders, or related organization on which interest payments would be allowable as costs but for the provisions of principle 1-2 (Reg. Sec. 405.419), is not subtracted in computing the amount of (1) and (2), in order that the proceeds from such loans be treated as a part of the provider's equity capital. In computing the amount of equity capital upon which a return is allowable, investment in facilities is recognized on the basis of the historical cost, or other basis, used for depreciation and other purposes under the health insurance program. For purposes of computing the allowable return the amount of equity capital is the average investment during the reporting period. The rate of return allowed, as derived from time to time based upon interest rates in accordance with this principle, is determined by the Social Security Administration and communicated through intermediaries. Return on investment as an element of allowable costs is subject to apportionment in the same manner as other elements of allowable costs. For the purposes of this regulation, the term "proprietary providers" is intended to distinguish providers, whether sole proprietorships, partnerships, or corporations, that are organized and operated with the expectation of earning profit for the owners, from other providers that are organized and operated on a nonprofit basis.



GENERAL PRINCIPLES OF REIMBURSEMENT*

2-1 Cost Related to Patient Care (Reg. Sec. 405.451)

Principle

All payments to providers of services must be based on the "reasonable cost" of services covered under title XVIII of the Act and related to the care of beneficiaries. Reasonable cost includes all necessary and proper costs incurred in rendering the services, subject to principles relating to specific items of revenue and cost.

Definitions

(1) *Reasonable Cost.* Reasonable cost of any services must be determined in accordance with regulations establishing the method or methods to be used, and the items to be included. The regulations in this subpart take into account both direct and indirect costs of providers of services. The objective is that under the methods of determining costs, the costs with respect to individuals covered by the program will not be borne by individuals not so covered, and the costs with respect to individuals not so covered will not be borne by the program. These regulations also provide for the making of suitable retroactive adjustments after the provider has submitted fiscal and statistical reports. The retroactive adjustment will represent the difference between the amount received by the provider during the year for covered services from both title XVIII and the beneficiaries and the amount determined in accordance with an accepted method of cost apportionment to be the actual cost of services rendered to beneficiaries during the year.

(2) *Necessary and proper costs.* Necessary and proper costs are costs which are appropriate and helpful in developing and maintaining the operation of patient care facilities and activities. They are usually

costs which are common and accepted occurrences in the field of the provider's activity.

Application

(1) It is the intent of title XVIII of the Act that payments to providers of services should be fair to the providers, to the contributors to the health-insurance trust funds, and to other patients.

(2) The costs of providers' services vary from one provider to another and the variations generally reflect differences in scope of services and intensity of care. The provision in title XVIII of the Act for payment of reasonable cost of services is intended to meet the actual costs, however widely they may vary from one institution to another. This is subject to a limitation where a particular institution's costs are found to be substantially out of line with other institutions in the same area which are similar in size, scope of services, utilization, and other relevant factors.

(3) The determination of reasonable cost of services must be based on cost related to the care of beneficiaries of title XVIII of the Act. Reasonable cost includes all necessary and proper expenses incurred in rendering services, such as administrative costs, maintenance costs, and premium payments for employee health and pension plans. It includes both direct and indirect costs and normal standby costs. However, where the provider's operating costs include amounts not related to patient care, or specifically not reimbursable under the program, such amounts will not be allowable. The reasonable cost basis of reimbursement contemplates that the providers of services would be reimbursed the actual costs of providing quality care however widely the actual costs may vary from provider to provider and from time to time for the same provider.

*AUTHORITY: 20 CFR 405, §§ 405.401-405.454 issued under secs. 1102, 1814(b), 1861(v), and 1871, 49 Stat. 647, as amended, 79 Stat. 296, 79 Stat. 322, 79 Stat. 331; 42 U.S.C. 1302, 1395 et seq.

2-2 Determination of Cost of Services to Beneficiaries (Reg. Sec. 405.452)

Principle

Total allowable costs of a provider shall be apportioned between program beneficiaries and other patients so that the share borne by the program is based upon actual services received by program beneficiaries. To accomplish this apportionment, the provider shall have the option of either of the two following methods:

(1) *Departmental method.* The ratio of beneficiary charges to total patient charges for the services of each department is applied to the cost of the department.

(2) *Combination method.* The cost of "routine services" for program beneficiaries is determined on the basis of average cost per diem of these services for all patients; to this is added the cost of ancillary services used by beneficiaries, determined by apportioning the total cost of ancillary services on the basis of the ratio of beneficiary charges for ancillary services to total patient charges for such services.

Definitions

(1) *Apportionment.* Apportionment means an allocation or distribution of allowable cost between the beneficiaries of the health insurance program and other patients.

(2) *Routine services.* Routine services means the regular room, dietary, and nursing services, minor medical and surgical supplies, and the use of equipment and facilities for which a separate charge is not customarily made.

(3) *Ancillary services.* Ancillary services or special services are the services for which charges are customarily made in addition to routine services.

(4) *Charges.* Charges refers to the regular rates for various services which are charged to both beneficiaries and other paying patients who receive the services. Implicit in the use of charges as the basis for apportionment is the objective that charges for services be related to the cost of the services.

(5) *Cost.* Cost refers to reasonable cost as described in principle 2-1 (Reg. Sec. 405.451).

(6) *Ratio of beneficiary charges to total charges on a departmental basis.* Ratio of beneficiary charges to total charges on a departmental basis, as applied to inpatients, means the ratio of inpatient charges to

beneficiaries of the health insurance program for services of a revenue-producing department or center to the inpatient charges to all patients for that center during an accounting period. After each revenue-producing center's ratio is determined, the cost of services rendered to beneficiaries of the health insurance program is computed by applying the individual ratio for the center to the cost of the related center for the period.

(7) *Average cost per diem for routine services.* Average cost per diem for routine services means the amount computed by dividing the total allowable inpatient cost for routine services by the total number of inpatient days of care (excluding newborn days where nursery costs are excluded from routine service costs) rendered by the provider in the accounting period.

(8) *Ratio of beneficiary charges for ancillary services to total charges for ancillary services.* Ratio of beneficiary charges for ancillary services to total charges for ancillary services, as applied to inpatients, means the ratio of the total inpatient charges for covered ancillary services rendered to beneficiaries of the health insurance program to the total inpatient charges for ancillary services to all patients during an accounting period. This ratio is applied to the allowable inpatient ancillary costs for the period to determine the amount of reimbursement to a provider for the covered ancillary services rendered to beneficiaries.

Application

(1) *Objective.* (i) The law provides that the costs with respect to individuals covered by the health insurance program will not be borne by individuals not so covered, and, conversely, that costs with respect to individuals who are not under the program will not be borne by the program.

(ii) The cost of services to beneficiaries of the health insurance program may be determined by either of the alternative methods, that is selected by a provider; however, the objective of whatever method of apportionment is used will be to approximate as closely as practicable the actual cost of services rendered.

(iii) The two methods of apportionment available for use in determining the cost of services rendered to beneficiaries of the program have as their goal the

allocation of the total allowable costs between the beneficiaries and other patients in as equitable a manner as possible. Under these methods, if it is found that beneficiaries receive more than the average amount of services, the providers would receive reimbursement greater than average cost for all patients. Conversely, if the beneficiaries receive less than the average amount

of services, the providers would be reimbursed accordingly for the services rendered.

(2) *Departmental method.* The following illustrates how apportionment based on the ratio of beneficiary charges to total charges applied to cost on a departmental basis would be determined, using only inpatient data.

Hospital A

Department	Charges to program beneficiaries	Total charges	Ratio of beneficiary charges to total charges	Total cost	Cost of beneficiary services
			<i>Percent</i>		
Routine services.....	\$140,000	\$600,000	23½%	\$630,000	\$147,000
X-ray.....	24,000	100,000	24	75,000	18,000
Operating room.....	20,000	70,000	28½%	77,000	22,000
Laboratory.....	40,000	140,000	28½%	98,000	28,000
Pharmacy.....	20,000	60,000	33½%	45,000	15,000
Others.....	6,000	30,000	20	25,000	5,000
Total.....	\$250,000	\$1,000,000		\$950,000	\$235,000

The total reimbursements for services rendered by the provider to the beneficiaries would be \$235,000.

(3) *Combination method*—(i) *Using cost finding.* A provider may, at its option, elect to be reimbursed on the average cost per diem for the cost of routine services, with apportionment of the cost of ancillary services on the basis of the ratio of beneficiary charges to total patient charges applied to the cost of all such ancillary services. The cost of the ancillary services rendered to beneficiaries of the program is determined by computing the ratio of total inpatient charges for ancillary services to beneficiaries to the total inpatient ancillary charges to all patients. This ratio is then applied to the total allowable cost of inpatient ancillary services.

Combination Method as Employed by Hospital B

Statistical and financial data:

Total inpatient days for all patients.....	30,000
Inpatient days applicable to beneficiaries.....	7,500
Inpatient routine services—total allowable cost..	\$600,000
Inpatient ancillary services—total allowable cost.	\$320,000
Inpatient ancillary services—total charges.....	\$400,000
Inpatient ancillary services—charges for services to beneficiaries.....	\$80,000

COMPUTATION OF COST APPLICABLE TO PROGRAM

Average cost per diem for routine services:

\$600,000 ÷ 30,000 days = \$20 per diem.

Cost of routine services rendered to beneficiaries:

\$20 per diem × 7,500 days..... \$150,000

Combination Method as Employed by Hospital B—Continued

COMPUTATION OF COST APPLICABLE TO PROGRAM—Continued

Ratio of beneficiary charges to total charges for all ancillary services:

\$80,000 ÷ \$400,000 = 20%.

Cost of ancillary services rendered to beneficiaries:

20% × \$320,000..... 64,000

Total cost of beneficiary services..... \$214,000

(ii) *Using estimated percentage.* The provider has an option at the beginning of the program of obtaining from the intermediary and utilizing an estimated rather than a computed basis for apportioning cost between routine and ancillary services. Where a provider either elects this option or is unable to make the necessary computations by cost-finding methods as indicated in principle 2-3 (Reg. Sec. 405.453), the intermediary will estimate the appropriate percentage of the provider's allowable cost that represents routine service costs and the appropriate percentage that represents the ancillary service costs. These percentages are to be based upon study, analysis, and judgment by the intermediary and designed to approximate the result that a cost-finding method would have produced for the particular provider. The use of estimated percentages would apply only to cost reports for periods ending before January 1, 1968. For subsequent periods, the use of cost-finding methods as described in principle 2-3 (Reg. Sec. 405.453) will be required for the apportionment of allowable costs.

Estimated Percentages Employed by Hospital C

Statistical and financial data:

Total inpatient days for all patients.....	35,000
Inpatient days applicable to beneficiaries....	5,000
Total allowable inpatient cost.....	\$1,000,000
Estimated percent for routine inpatient services	70
Estimated percent for ancillary inpatient services	30
Inpatient ancillary services:	
Total charges.....	\$400,000
Charges for services to beneficiaries.....	\$80,000

COMPUTATION OF COST APPLICABLE TO PROGRAM

Average cost per diem for routine services:

$$70\% \times \$1,000,000$$

$$= \$700,000 \text{ (routine service cost).}$$

$$\$700,000 \div 35,000 \text{ days} = \$20 \text{ per diem.}$$

Cost of routine services rendered to beneficiaries:

$$\$20 \text{ per diem} \times 5,000 \text{ days} = \$100,000$$

Ratio of beneficiary charges to total charges for all ancillary services:

$$\$80,000 \div \$400,000 = 20\%.$$

Cost of ancillary services rendered to beneficiaries:

$$30\% \times \$1,000,000$$

$$= \$300,000 \text{ (ancillary services costs).}$$

$$20\% \times \$300,000 = 60,000$$

$$\text{Total cost of beneficiary services} = \$160,000$$

(4) *Option to use departmental method or combination method for the first reporting period.* The provider has the option of using either the departmental method or the combination method for the first reporting period. Thereafter, a provider may change from one to the other method provided a request is made to the intermediary before the end of the first month of the period for which the change is to be applied and such request is approved.

(5) *Temporary methods of apportionment.* (i)

The intermediary may find that a provider is unable to apply either the departmental method or the combination method employing cost finding or estimated percentages. In such case, the intermediary can authorize

the provider to use, on a temporary basis, an apportionment based on the ratio of beneficiary inpatient charges to total inpatient charges applied to the total cost of all services. This would permit the provider time to establish the records necessary for applying either of the basic alternative methods of apportionment in the next accounting period. In some cases the intermediary may determine that a provider is unable to employ this temporary method of apportionment based on the ratio of beneficiary inpatient charges to total inpatient charges applied to total inpatient cost. In such a case any other method determined by the intermediary to be reasonable may be used on a temporary basis. Any temporary method of apportionment may not be used to cover more than one cost reporting period.

Example. The following illustration demonstrates the apportionment of cost based on the ratio of beneficiary inpatient charges to all inpatient charges computed on a total basis for all inpatient services.

Hospital D

Financial data:

Inpatient services:

$$\text{Total allowable cost} = \$950,000$$

$$\text{Total charges} = \$1,000,000$$

$$\text{Charges for beneficiary services} = \$200,000$$

COMPUTATION OF COST OF BENEFICIARY INPATIENT SERVICES

Ratio of beneficiary charges to total charges:

$$\$200,000 \div \$1,000,000 = 20\%.$$

Cost of services rendered to beneficiaries:

$$20\% \times \$950,000 = \$190,000$$

(ii) Whenever authorization is given to apportion costs by a method other than one of the two basic alternative methods, such authorization would be considered to be a temporary expediency to cover only one accounting period. It would be available to a provider only after diligent efforts have been made by the provider to apportion its costs based upon either of the approved methods of apportionment.

2-3 Adequate Cost Data and Cost Finding (Reg. Sec. 405.453)

Principle

Providers receiving payment on the basis of reimbursable cost must provide adequate cost data. This must be based on their financial and statistical records which must be capable of verification by qualified auditors. The cost data must be based on an approved method of cost finding and on the accrual basis of accounting. However, where governmental institutions operate on a cash basis of accounting, cost data based on such basis of accounting will be acceptable, subject to appropriate treatment of capital expenditures.

Definitions

(1) *Cost finding.* Cost finding is the process of recasting the data derived from the accounts ordinarily kept by a provider to ascertain costs of the various types of services rendered. It is the determination of these costs by the allocation of direct costs and proration of indirect costs.

(2) *Accrual basis of accounting.* Under the accrual basis of accounting, revenue is reported in the period when it is earned, regardless of when it is collected, and expenses are reported in the period in which they are incurred, regardless of when they are paid.

Adequacy of cost information

Adequate cost information must be obtained from the provider's records to support payments made for services rendered to beneficiaries. The requirement of adequacy of data implies that the data be accurate and in sufficient detail to accomplish the purposes for which it is intended. Adequate data capable of being audited is consistent with good business concepts and effective and efficient management of any organization, whether it is operated for profit or on a nonprofit basis. It is a reasonable expectation on the part of any agency paying for services on a cost-reimbursement basis. In order to provide the required cost data and not impair comparability, financial and statistical records should be maintained in a manner consistent from one period to another. However, a proper regard for consistency need not preclude a desirable change in accounting procedures when there is reason to effect such change.

Cost finding methods

After the close of the accounting period, one of the following methods of cost finding is to be used to determine the actual costs of services rendered during that period.

(1) *Step-down method.* This method recognizes that services rendered by certain nonrevenue-producing departments or centers are utilized by certain other nonrevenue-producing centers as well as by the revenue-producing centers. All costs of nonrevenue-producing centers are allocated to all centers which they serve, regardless of whether or not these centers produce revenue. The cost of the nonrevenue-producing center serving the greatest number of other centers, while receiving benefits from the least number of centers, is apportioned first. Following the apportionment of the cost of the nonrevenue-producing center, that center will be considered "closed" and no further costs are apportioned to that center. This applies even though it may have received some service from a center whose cost is apportioned later. Generally when two centers render service to an equal number of centers while receiving benefits from an equal number, that center which has the greatest amount of expense should be allocated first.

(2) *Other methods—(i) The double-apportionment method.* The double-apportionment method may be used by a provider upon approval of the intermediary. This method also recognizes that the nonrevenue-producing departments or centers render services to other nonrevenue-producing centers as well as to revenue-producing centers. A preliminary allocation of the costs of nonrevenue-producing centers is made. These centers or departments are not "closed" after this preliminary allocation. Instead, they remain "open," accumulating a portion of the costs of all other centers from which services are received. Thus, after the first or preliminary allocation, some costs will remain in each center representing services received from other centers. The first or preliminary allocation is followed by a second or final apportionment of expenses involving the allocation of all costs remaining in the nonrevenue-producing functions directly to revenue-producing centers.

(ii) *More sophisticated methods.* A more sophisticated method designed to allocate costs more accurately may be used by the provider upon approval of the intermediary. However, having elected to use the double-apportionment method, the provider may not thereafter use the step-down method without approval of the intermediary. Request for the approval must be made on a prospective basis and must be submitted before the end of the first month of the prospective reporting period. Likewise, once having elected to use a more sophisticated method, the provider may not thereafter use either the double-apportionment or step-down methods without similar request and approval.

(3) *Temporary method for initial period.* If the provider is unable to use either cost-finding method

when it first participates in the program, it may apply to the intermediary for permission to use some other acceptable method which would accurately identify costs by department or center, and appropriately segregate inpatient and outpatient costs. Such other method may be used for cost reports covering periods ending before January 1, 1968.

Accounting basis

The cost data submitted must be based on the accrual basis of accounting which is recognized as the most accurate basis for determining costs. However, governmental institutions that operate on a cash basis of accounting may submit cost data on the cash basis subject to appropriate treatment of capital expenditures.

2-4 Payments to Providers (Reg. Sec. 405.454)

Principle

Providers of services will be paid the reasonable cost of services furnished to beneficiaries. Interim payments approximating the actual costs of the provider will be made on the most expeditious basis administratively feasible but not less often than monthly. A retroactive adjustment based on actual costs will be made at the end of the reporting period. At the request of the provider, payment will be made on a basis designed to reimburse currently for services rendered to beneficiaries.

Amount and frequency of payment

Title XVIII of the Act states that providers of services will be paid the reasonable cost of services furnished to beneficiaries. Since actual costs of services cannot be determined until the end of the accounting period, the providers must be paid on an estimated cost basis during the year. While the law provides that interim payments shall be made no less often than monthly, intermediaries are expected to make payments on the most expeditious basis administratively feasible. Whatever estimated cost basis is used for determining interim payments during the year, the intent is that the interim payments shall approximate actual costs as nearly as is practicable so that the retroactive adjustment based on actual costs will be as small as possible.

Interim payments during initial reporting period

At the beginning of the program or when a provider first participates in the program, it will be necessary to establish interim rates of payment to providers of services. Once a provider has filed a cost report under the health insurance program, the cost report may be used as a basis for determining the interim rate of reimbursement for the following period. However, since initially there is no previous history of cost under the program, the interim rate of payment must be determined by other methods, including the following:

(1) Where the intermediary is already paying the provider on a cost or cost-related basis, the intermediary will adjust its rate of payment to the program's principles of reimbursement. This rate may be either an amount per inpatient day, or a percent of the provider's charges for services rendered to the program's beneficiaries.

(2) Where an organization other than the intermediary is paying the provider for services on a cost or cost-related basis, the intermediary may obtain from that organization or from the provider itself the rate of payment being used and other cost information as may be needed to adjust that rate of payment to give recognition to the program's principles of reimbursement.

(3) Where no organization is paying the provider on a cost or cost-related basis, the intermediary will obtain the previous year's financial statement from the provider. By analysis of such statement in the light of the principles of reimbursement, the intermediary will compute an appropriate rate of payment.

(4) After the initial interim rate has been set, the provider may at any time request, and be allowed, an appropriate increase in the computed rate, upon presentation of satisfactory evidence to the intermediary that costs have increased. Likewise, the intermediary may adjust the interim rate of payment if it has evidence that actual costs may fall significantly below the computed rate.

Interim payments for new providers

(1) Newly established providers will not have cost experience on which to base a determination of an interim rate of payment. In such cases, the intermediary will use the following methods to determine an appropriate rate:

(i) Where there is a provider or providers comparable in substantially all relevant factors to the provider for which the rate is needed, the intermediary will base an interim rate of payment on the costs of the comparable provider.

(ii) If there are no substantially comparable providers from whom data are available, the intermediary will determine an interim rate of payment based on the budgeted or projected costs of the provider.

(2) Under either method, the intermediary will review the provider's cost experience after a period of 3 months. If need for an adjustment is indicated, the interim rate of payment will be adjusted in line with the provider's cost experience.

Interim payments after initial reporting period

Interim rates of payment for services provided after the initial reporting period will be established on the basis of the cost report filed for the previous year cov-

ering health insurance services. The current rate will be determined—whether on a per diem or percentage of charges basis—using the previous year's costs of covered services and making any appropriate adjustments required to bring, as closely as possible, the current year's rate of interim payment into agreement with current year's costs. This interim rate of payment may be adjusted by the intermediary during an accounting period if the provider submits appropriate evidence that its actual costs are or will be significantly higher than the computed rate. Likewise, the intermediary may adjust the interim rate of payment if it has evidence that actual costs may fall significantly below the computed rate.

Retroactive adjustment

(1) Title XVIII of the Act provides that providers of services shall be paid amounts determined to be due, but not less often than monthly, with necessary adjustments due to previously made overpayments or underpayments. Interim payments are made on the basis of estimated costs. Actual costs reimbursable to a provider cannot be determined until the cost reports are filed and costs are verified. Therefore, a retroactive adjustment will be made at the end of the reporting period to bring the interim payments made to the provider during the period into agreement with the reimbursable amount payable to the provider for the services rendered to program beneficiaries during that period.

(2) In order to reimburse the provider as quickly as possible, an initial retroactive adjustment will be made as soon as the cost report is received. For this purpose, the costs will be accepted as reported—unless there are obvious errors or inconsistencies—subject to later audit. When an audit is made and the final liability of the program is determined, a final adjustment will be made.

(3) To determine the retroactive adjustment, the amount of the provider's total allowable cost apportioned to the program for the reporting year is com-

puted. This is the total amount of reimbursement the provider is due to receive from the program and the beneficiaries for covered services rendered during the reporting period. The total of the interim payments made by the program in the reporting year and the deductibles and coinsurance amounts receivable from beneficiaries is computed. The difference between the reimbursement due and the payments made is the amount of the retroactive adjustment.

Provision for current financing

(1) In addition to the basic procedure for payment to a provider following the submission of bills to the intermediary, payment will be made upon request by the provider on a basis designed to reimburse currently for services furnished to beneficiaries. The amount of such payment will be computed by the intermediary initially on an estimated basis and periodically adjusted to represent the average level of services unreimbursed by the basic payment procedure.

(2) A study will be made of the possibility that a financial requirement in the production of services arises prior to the rendition of services to beneficiaries and is not being met by the program. Among the factors to be considered in the study will be the extent to which outlays for consumable items for which payment may be made in advance of rendition of services are offset by outlays for other items, such as wages and salaries, which ordinarily are not made until after services are rendered.

Cost reporting period

For cost-reporting purposes, the program will require submission of annual reports covering a 12-month period of operations based upon the provider's accounting year. At the option of the provider, however, during the first year of the program a short period report beginning July 1, 1966, and ending with the provider's accounting year may be submitted, provided such report covers at least 6 months.

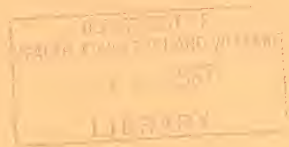








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**HEALTH
INSURANCE
FOR THE AGED**

PRINCIPLES OF REIMBURSEMENT FOR SERVICES BY HOSPITAL-BASED PHYSICIANS



U.S. DEPARTMENT OF
HEALTH, EDUCATION, AND WELFARE
SOCIAL SECURITY ADMINISTRATION

HIM-6 (2-67)



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*AUTHORITY: 20 CFR 405, § 405.480-405.488 issued under secs. 1102, 1814(b), 1833(a), 1861(v), and 1871, 49 Stat. 647, as amended, 79 Stat. 296, 79 Stat. 322, 79 Stat. 331; 49 U.S.C. 1302, 1395 et seq.



REIMBURSEMENT FOR SERVICES BY HOSPITAL-BASED PHYSICIANS UNDER TITLE XVIII OF THE SOCIAL SECURITY ACT AS AMENDED (PUBLIC LAW 89-97)*

INTRODUCTION—(Reg. Sec. 405.480)

General. The Health Insurance for the Aged Act establishes two separate health insurance programs for the elderly. One provides hospital insurance protection to nearly all the aged financed largely through social security taxes. The other provides supplementary medical insurance to aged people who enroll and agree to pay monthly premiums, that are matched with amounts from Federal general revenues.

Sources of benefit payments. Under the law, benefit payments for the services of physicians (except for services of residents and interns under professionally-approved training programs) furnished to individual patients are under the supplementary medical insurance program. However, some of the services which hospital-based physicians perform are clearly not furnished to an individual patient. To the extent that the cost of such services is borne by the hospital, reimbursement will be made to the hospital under the hospital insurance program or, in certain cases, as a hospital cost under the supplementary medical insurance program.

Applicability of principles of reimbursement. The principles deal with the identification of the source and amount of benefit payments under the program for services performed by physicians (other than interns and residents) in a hospital setting under circumstances where physicians typically are salaried or receive compensation from or through the hospital under arrangements such that the physician is paid an agreed amount or the hospital remits to him an agreed portion of the collections from patients and the hospital collects the funds from patients either in its own right or as agent for the physician. These principles establish criteria for distinguishing between those services of physicians who are so compensated which are reimbursable to hospitals and such physicians' services to patients reimbursed under the supplementary medical insurance program. The principles also establish a basis for determining the reasonable charges for physicians' services to patients in situations where, under existing arrangements between hospitals

and physicians, billings to patients have not separately identified charges for physicians' services and charges for hospital services. (Where charges for physicians' services to patients have been identified separately from charges for hospital services, the customary charges for physicians' services thus will have been established and a basis afforded for determining the reasonable charges for such services. Where, for example, as is sometimes the case in the arrangements between hospital-based physicians and hospitals, especially, but not exclusively, in the arrangements between teaching hospitals and surgeons, among others, the charges for the physicians' services to the patient are separately identified, the determination of the reasonable charges for such services will take into account customary charges of such physicians so established.) Finally, the principles establish a basis for ascertaining the customary charges for a physician's services to patients in situations where, under the previously existing arrangement between the hospital and the physician, charges to patients had not been separately identified but where under a modification of the previously existing arrangement the hospital and the physician agree to bill patients separately for their respective services.

Arrangements for services of hospital-based physicians. Hospitals in the United States have in force a wide variety of arrangements for the compensation of hospital-based physicians. The Health Insurance for the Aged program does not require change in the substance of these arrangements, whether the arrangements call for compensation by way of salary, or a percentage, or in any other manner, or whether payments are received by the hospital (either in its own right or as agent for the physician) or are received directly by the physician.

In many cases, a physician contracts with a hospital to provide only his own professional services, the hospital assuming the cost of supporting personnel (who, in this case, are hospital employees) and bearing the expense of furnishing space, supplies, and the like. Sometimes, however, the physician assumes some or all of these costs. In some instances, the arrangement may constitute a concession or lease, the physician employing the supporting personnel and bearing all other

* Authority: 20 C.F.R. 405, 405.480-405.488 issued under secs. 1102, 1814(b), 1833(a), 1861(v) and 1871, 49 Stat. 647, as amended, 79 Stat. 296, 79 Stat. 322, 79 Stat. 331; 49 USC 1302, 1395 CT Seq.

expenses, including a payment to the hospital for the use of space.

Types of services rendered. Many hospitals retain physicians on a full-time basis as, for example, in the fields of pathology, psychiatry, anesthesiology, and radiology, and in many instances (especially in teaching hospitals) in other fields of medical specialization as well. The functions of these physicians vary widely. In some cases they devote full time to education or administration. Conversely, some are exclusively concerned with patient care. Any one of these physicians may be engaged in a variety of activities including teaching, research, administration, supervision of professional or technical personnel, service on hospital committees, and other hospital-wide activities, as well as direct personal health services to individual patients. Sometimes the hospital's arrangement is made with a group of physicians who assume joint responsibility for discharging agreed-upon duties.

Provisions for remuneration. The compensation to the physician generally is either on a salary basis, a percent of the gross income received from the patients for the particular services (usually a group of related services—all those performed in a radiology department, for example), or a percent of the net income (gross income less related expenses) received from patients, or some modification or combination of these (such as percentage with a guaranteed minimum). Generally the hospital collects the charges for the services of these physicians and their supporting personnel, acting in some cases in its own right, in some as agent for the physician. Where the arrangement between the hospital and the physician is that the compensation to the physician is on a salary or percentage of income basis, and the parties to the arrangement have thus agreed between themselves on the amount or the measure of compensation to be received by the physician for his services, the sum of the payments, with

respect to the physician's services, under both the hospital insurance program and the supplementary medical insurance program (including deductible and coinsurance amounts payable by beneficiaries) should approximate that portion of the agreed upon compensation which is attributable to covered services. Some hospitals, moreover, have arrangements with medical schools or other organizations under which physicians receive compensation from such organizations for services the physicians provide to hospital patients. The remuneration of physicians from such sources may be included in determining reasonable charges for physicians' services in accordance with principle 5 (Reg. Sec. 405.485).

Identification of types of services for purposes of program payments. However the billing is handled and whatever the method of distributing the proceeds between the hospital and the physician, it has been the almost universal practice to make a single charge to the patient for each of these services. In order to make payments under title XVIII of the Act, however, it is necessary where billing is by or through the hospital, to distinguish between the medical and surgical services rendered by a physician to a patient, on the one hand, and the hospital services (including physicians' services for the hospital), on the other. This is required because the payments will come from different trust funds, the payments will usually be handled by different intermediaries, and the methods of determining the two payments will differ materially. Thus, there are two sources of payment under the health insurance program for services furnished to beneficiaries covered under title XVIII of the Act. The hospital and the physician may, however, if they wish, pool the two payments where received by the hospital in its own right or as agent for the physician and may distribute the proceeds in accordance with their preexisting arrangement, or in any other way on which they may agree.

PRINCIPLES OF REIMBURSEMENT*

PRINCIPLE 1

Noninterference by Federal Government (Reg. Sec. 405.481)

It is not the function of the health insurance programs established under title XVIII of the Act to determine the arrangement which a hospital and a hospital-based physician may enter into for the compensation of the physician. The Secretary will not specify or influ-

ence the provisions of the contract or arrangement between hospitals and hospital-based physicians. The hospital and physician can continue to negotiate all aspects of their arrangement to their mutual satisfaction. These principles are designed to give recognition to the arrangement entered into by a hospital and a physician by establishing criteria for determining, within the framework of the arrangement, amounts payable under the hospital insurance program and amounts payable under the supplementary medical insurance program to the end that the total payments with respect to the physicians' services to the hospital and for the patient are related as closely as is possible to the level of compensation the parties have agreed upon.

*Authority: 20 C.F.R. 405, 405.480-405.488 issued under secs. 1102, 1814(b), 1833(a), 1861(v) and 1871, 49 Stat. 647, as amended, 79 Stat. 296, 79 Stat. 322, 79 Stat. 331; 49 USC 1302, 1395 CT seq.

PRINCIPLE 2

Program Payments for Physicians' Services to Hospitals and to Individual Patients (Reg. Sec. 405.480)

Principle. Whatever the arrangement may be between hospital and physician, the law requires that medical and surgical services rendered to a covered individual by a hospital-based physician be reimbursed only under the supplementary medical insurance program—Part B of title XVIII of the Act. The costs to a hospital for services furnished in a hospital by a physician which are not professional services to a patient are included in the reasonable cost reimbursement to the hospital.

Physicians' services to patients. Title XVIII of the Act specifically excludes from hospital cost reimbursement under Part A the cost of medical or surgical services provided by a physician, resident, or intern except for those services rendered by interns or residents in approved teaching programs. Therefore, compensation paid by the hospital to the hospital-based physician cannot be included in hospital reimbursable cost to the extent that it represents compensation for physicians' services described in Principle 3 (Reg. Sec. 405.483). Physicians' services, as defined in section 1861(q) of the Act, means "professional services performed by physicians, including surgery, consultation, and home, office and institutional calls * * *."

PRINCIPLE 3

Physician Service Under Part B (Reg. Sec. 405.483)

Principle. A professional service rendered by a physician to a hospital patient that can be reimbursed only under the supplementary medical insurance program (Part B of title XVIII of the Act), as distinguished from his professional services which are of benefit to patients generally, means an identifiable service requiring performance by a physician in person, which contributes to the diagnosis of the condition of the patient with respect to whom the charge under the supplementary medical insurance program is to be recognized, or contributes to the treatment of such patient.

Recordation and billing of charges on item-by-item basis. The component of the hospital-based physician's services for which reimbursement must be made under Part B of title XVIII of the Act, the supplementary medical insurance program, is only that part of his professional services with respect to which he is personally involved in the provision of services to individual patients as distinct from other professional services he may render in the hospital setting, such as teaching, research, performance of autopsies, committee work, quality control activities and administration. Compliance with this principle for various types of services rendered by hospital-based physicians normally will require:

(1) determination with respect to each separate service or type of service rendered, of what part may properly be charged under the supplementary medical insurance program,

(2) compilation of the results of these determinations in the form of a schedule either of amounts or percentages applicable to separate services or types of services, and

(3) recordation of such charges on an item-by-item basis for each service rendered to a patient.

Optional method of recordation and billing on a uniform-percentage basis. (1) Application of the item-by-item method may present special problems in the case of a particular hospital department. This is illustrated by pathology laboratory services and radiology services, which involve a high volume of individual procedures, variation in the extent of involvement in services on the part of technicians and others and on the part of the physician, and difficulty in distinguishing between professional activities which are of general benefit to all patients and those performed directly for an identifiable patient. Where the physician participates personally in some procedures and not in others by virtue of quality control activities or because his professional concern is directed to the result in a given case, it may be difficult to ascertain the presence or absence of a specific quantum of professional activity in an individual case. Moreover, the

assigning of the appropriate amount of "professional component" to a particular procedure or test for a particular patient receiving the benefit of the physician's service, as defined in this principle, may not only result in inequality of charges among patients but also may present an undue task of recordation. Administratively costly and impractical requirements could ensue in collecting the data needed for presentation of bills involving minimal charges on an item-by-item basis to individual patients. Under these conditions, it may not be administratively practical for the physician, the hospital and the Part B carrier to keep track of appropriate professional charges on an item-by-item and patient-by-patient basis.

(2) With respect to pathology services, for example, an individual entitled to Part B benefits under title XVIII of the Social Security Act (in connection with a hospital stay, or in connection with a series of outpatient diagnostic tests) will, on the average, have multiple laboratory procedures which in the aggregate permit the assumption that at some point with respect to at least some of the laboratory services there has been "an identifiable service requiring performance by a physician in person."

(3) In order to facilitate administration, provide a better cost control, and to assure a practical basis for handling charges to individual patients, an optional method of recordation and billing may be elected upon agreement by the physician and the hospital in appropriate cases. Under this optional method, the component of the physician's services to patients would be determined for all medicare patients through application of a uniform percentage to the total charges for such services in a particular department, with the percentage used being designed to produce in the aggregate a measurement of the professional component attributable to patient services which would not be significantly different in amount from that produced by the method of itemization of detailed measurement of such components reflecting variation in the factor of personal participation of the physician in each individual procedure for each individual patient. The percentage factor will be considered reasonable if it can be shown that it does not result from attributing as medical services to patients the costs of teaching, research, administration, and other services that are clearly reimbursable under the hospital insurance program.

(4) Election to use the optional method does not alter the applicability of the principles as the basic criterion for distinguishing professional services chargeable under the supplementary medical insurance program from those to be included in the hospital's reimbursable costs. The optional method is not available where it would result in a charge to medicare patients for services which are not ordinarily furnished by the physicians of the department of the hospital to hospital patients utilizing the services of that department.

PRINCIPLE 4

Hospital-Physician Agreements for Physician Compensation (Reg. Sec. 405.485)

Principle. For purposes of reimbursement, intermediaries and carriers will respect, within reasonable limits, an agreement between a hospital and a physician concerning the portion of the physician's compensation which, if he is engaged in the care of individual patients, is to be attributed to such care, and the portion which is to be attributed to service to the institution. The procedure hospitals and physicians are to follow in obtaining review of their agreement by intermediaries is described in principle 7 (Reg. Sec. 405.487). The amount attributed to the care of patients will, to the extent of services rendered to supplementary medical insurance beneficiaries (identified in accordance with principle 3 (Reg. Sec. 405.483)), be recognized as proper charges to such patients, reimbursable under the supplementary medical insurance program. The amount attributed to service to the institution will be recognized as a cost which is reimbursable to the hospital.

Scope and effect of agreement. Typically, contracts between hospital-based physicians and hospitals pro-

vide for the payment of an aggregate amount (in the form of a salary, a percentage arrangement, or on some other basis) to the physician for all of his services within the institution without a service-by-service itemization. Where the physician is on salary and normally spends full time in administration of departmental affairs, the full salary may be considered a reimbursable hospital cost item and medicare will bear its proportionate share of such cost. Where a salaried physician devotes only part of his time to institutional affairs and also renders an appreciable volume of personal patient care, only part of his salary may be attributed to hospital costs since the law requires that "medical or surgical services" must be excluded in determining a hospital's reimbursable costs.

Allocation of compensation by parties. An agreement by the parties that a certain portion of the physician's compensation will be excluded from hospital costs and will be charged to those patients who are identified in accordance with principle 3 (Reg. Sec. 405.483) will be respected unless, because of the small portion of time the physician devotes to the personal care of patients, such an agreement could lead to unreasonable charges to such patients.

PRINCIPLE 5

Schedules of charges for Part B physician's services (Reg. Sec. 405.485)

Principle. Once the portion of a physician's compensation attributable to professional services to supplementary medical insurance beneficiaries has been determined, a schedule of charges can be developed. To be deemed reasonable the charges should be designed to yield in the aggregate, as nearly as may be possible, an amount equal to such portion of his compensation. As among the patients to be charged (identified in accordance with Principle 3 (Reg. Sec. 405.483)), the allocation of charges may be based on a schedule of relative values, on a uniform percentage of the charges made by the hospital or the physician to other patients for both professional and supporting components of the services, or on another method approved by the carrier as equitable.

Development of schedules. Since the present almost universal practice does not separate the professional services to individual patients from the other components of hospital-based physicians' services for purposes of determining the manner or amount of his compensation, it is necessary to devise a method for making this separation. The approach set forth in this section starts with the assumption that the present level of compensation of hospital-based physicians is reasonable. The assumption, of course, is open to challenge in any given case, and the carriers must deal with such challenges on the basis of prevailing rates of compensation in comparable institutions.

Over a period of time the schedules of charges will be subject to revision in the light of changes in the prevailing levels of compensation.

Development of charges on per diem basis. Some relatively few hospitals in which the hospital-based physicians are compensated by salary or other fixed amount of remuneration do not charge on a fee-for-service basis for each service provided a patient, but charge a fixed, all-inclusive rate, computed on a daily or other time basis or a per-visit basis, applicable uniformly to each patient without regard to the quantum of service required by the patient and without distinction between hospital services and physicians' services. Psychiatric hospitals, tuberculosis hospitals, and some governmental general hospitals commonly follow such a charge practice. Other hospitals use the fixed charge method for all services or only in connection with the services of certain of their departments while charging on a fee-for-service basis for the various services actually furnished to the patients in other departments. Where the billing by the hospital is on a per diem or other time period basis or on a per-visit basis, charges for the professional services of hospital-based physicians to patients may be computed on such a basis for program purposes. Under this method, after the apportionment of the physicians' compensation has been made in accordance with Principle 4 (Reg. Sec. 405.484), a per diem, per visit, or other unit charge can be developed, designed to yield in the aggregate, as nearly as may be possible, an amount equal to the physicians' compensation attributable to professional services to patients.

PRINCIPLE 6

Effect of physician's assumption of operating costs (Reg. Sec. 405.486)

Principle. Where a hospital-based physician himself bears some or all of the costs of operation of a hospital department and bills his patients directly rather than through the hospital, the reasonable charges for his services recognized under the supplementary medical insurance program will reflect the costs so borne by him. Where all the costs are to be borne by the physician, charges heretofore established for such services by agreement between the physician and the hospital may be acceptable as reasonable charges for purposes of the supplementary medical insurance program, but they will require adjustment either upward or downward if the hospital has been bearing a cost significantly greater or less than its share of the proceeds of such charges.

Billing for physician services. (1) The objective in determining reasonable charges where the physician bills patients directly is the same as that expressed in principle 5 (Reg. Sec. 405.485); to bring about as little change as possible (in the normal case) in the compensation the physician receives for his services in the hospital. Where the physician bills the patient directly, costs of operating the hospital department which are borne by the physician will be reflected in his reasonable charges which are compensable under the supplementary medical insurance program; the hospital will receive reimbursement through the hospital insurance program for those costs, if any, which it incurs. Where, however, a hospital initially pays some or all of the operating expenses of a hospital department (e.g., pays the salaries of nonprofessional personnel and purchases supplies and equipment), even though subsequently those items and services for which it pays the operating expenses are furnished for the use of the physician in return for an agreed upon payment by the physician to the hospital, such operating costs are reimbursable under the hospital insurance program as hospital costs, and are not to be reflected in the reasonable charges of the physician. Any payments received by the hospital under such an arrangement shall be treated as a reduction of allowable costs of the hospital reimbursable through the hospital insurance program.

(2) Where a hospital has been receiving, as its portion of the receipts for such services, significantly more or less than the costs the hospital has incurred in the provision of the services, this excess or shortage should not be transferred from the hospital to the physician merely because he decides to bill his patients directly. Since payment to the hospital is made on the basis of its reasonable costs for all hospital services, the transfer of such excess or shortage to the physician necessarily would alter the total cost of patient hospital

and medical care—a result which the legislation was not intended to bring about. The reasonable charges of a physician who enters into a lease or similar arrangement with a hospital under which the physician assumes the costs of operating the department and bills the patients directly would be based upon the remuneration he received for his services immediately prior to the leasing arrangement plus his reasonable costs of operation, taking into account the hospital's cost experience in providing such services. Reasonable charges, so determined, would be subject to appropriate future adjustment to take into account changing economic factors. Reference back to the remuneration formerly received by the physician from the hospital as a factor in determining his reasonable charges under the lease or similar arrangement is required to give effect to the provisions of the statute which direct that consideration be given, in determining reasonable charges, to the customary charges generally made by the physician for similar services. Where no pattern of customary charges has been established for the physician's professional services to patients other than the compensation he received from the hospital for his services, such compensation would serve as the basis for establishing the customary charge.

(3) Since prevailing charges of physicians in the locality for similar services also are to be considered in determining reasonable charges of a physician, the charges of nonhospital laboratories, clinics, and the like for similar services would be taken into account in determining whether or not the customary charges, established in accordance with these principles, are within the range of prevailing charges. The situations, however, are frequently not comparable because of the large volume, and consequent low unit cost, of a laboratory that performs all of the services required in a hospital. Although charges prevailing in non-hospital laboratories are to be taken into account, they will not be guides for determining reasonable charges in situations where they would produce an unreasonable result.

(4) Although the law excludes physicians' services from the definition of hospital services, it further provides that services of nonphysicians aiding physicians are not deemed to be the services of a physician and are covered under the hospital insurance plan whether they are furnished by the hospital or by a physician under an arrangement with the hospital which calls for billing for such services to be by or through the hospital exclusively. Where, therefore, billing for services of a hospital department, including the services of the physician in such department, is by or through the hospital, the charges for the physician's services to the patient and for the nonphysician components of the services furnished by the physician under his arrangement with the hospital shall be determined as provided

in paragraph (1) of this principle, and may be included in a single bill which identifies separately the amounts billed for the respective components of the services. The amount of the physician's charge attributable to the nonphysician components of the service represents a cost to the hospital which is reimbursable to the hospital. The amount attributable to the physician's services to the patient is the physician's charge compensable under the supplementary medical insurance program.

(5) Also, tangentially related to the issue of billing for services of hospital-based physicians is the question of billing for diagnostic or therapeutic items or services not furnished in a hospital department, but under arrangements made by the hospital with outside

laboratories for such items or services. Many hospitals, especially smaller hospitals do not maintain full laboratory facilities. Such institutions frequently enter into arrangements with independent outside laboratories for the performance of diagnostic procedures, as, for example, in the field of pathology. In such instances, typically, the laboratory bills the hospital for the services performed, and the hospital, under present practices, bills the patient. Services performed under such an arrangement would be included as inpatient hospital services, and the cost thereof—that is, the cost the hospital incurs in paying the laboratory's charges for the services—would, if reasonable, be reimbursable to the hospital.

PRINCIPLE 7

Maintenance of records and review of reasonable costs and charges (Reg. Sec. 405.487)

Principle. Hospitals and hospital-based physicians will be required to keep records and furnish information to substantiate the agreements they enter into with respect to the allocation of the compensation of the physicians.

Rationale to support agreements for allocation of compensation. (1) Where the agreement between the hospital and the physician reasonably allocates the physician's compensation between services covered as costs to be reimbursed to the hospital and those covered under the supplementary medical insurance program on a charges basis, it will generally be accepted if the parties concerned furnish an acceptable rationale for the allocation.

(2) Such allocation (made in accordance with principle 4 (Reg. Sec. 405.484)) should be capable of substantiation by the hospital and the physician. The parties' determination and supporting information should be reviewed by the hospital insurance intermediary and the carrier. The intermediary will be responsible

for the approval of the portion of the physician's compensation which has been determined by the parties to be a cost which is reimbursable to the hospital and the carrier will be responsible for the approval or disapproval of the parties' reasonable charge determination.

(3) If the parties do not come to an agreement, or if either the hospital insurance intermediary or the carrier believes that the rationale does not justify the parties' allocation between reimbursable hospital costs and medical insurance charges, it will notify the other so that coordinated action, if necessary, can be undertaken. The fiscal intermediary responsible for hospital cost reimbursement and the carrier responsible for payments under the supplementary medical insurance program will resolve the issue by negotiation if possible, otherwise by time studies or other suitable methods.

(4) Under these principles, it is recognized that a physician who serves two or more hospitals may under his agreements have significantly different allocations and consequently significantly different charges for the same service in the different hospitals served by him.

PRINCIPLE 8

Effect of principles (Reg. Sec. 405.488)

Nothing in the foregoing principles restricts the right of the physician (in the absence of his acceptance of an assignment by the patient) to determine the amount of his charge to the patient for his services, or restricts the hospital and the physician in providing for such disposition of the payments received from the health insurance programs and the beneficiaries under the programs as they may agree upon.

The total costs of hospital and medical services to inpatients and outpatients prior to the inauguration of

this program should not be increased solely by reason of the requirement for division of payments for the services of hospital-based physicians between the hospital insurance program and the supplementary medical insurance program.

The foregoing principles will, to the extent they are applicable, also govern reimbursement in cases where physicians have a financial arrangement of the kind referred to in the Introduction (Reg. Sec. 405.480) under "Applicability of Principles of Reimbursement" with an extended care facility or home health agency and where a hospital-based physician provides services to the hospital's outpatients.



ILLUSTRATIVE METHODOLOGIES

The methodology is described in a setting in which there is a single physician in the hospital's pathology or radiology or other department. Where there is more than one physician in a particular department, the term "physician" should be read as "physicians," and where quantitative factors are stated or derived they should be combined for all such physicians.

(a) *Separating hospital payments to physicians into the Part A and Part B components as the basis for determining Part B charges.* (1) Whether the physician and hospital agree to utilize the item-by-item recordation and billing method or the optional method described in principle 3 (Reg. Sec. 405.483), it is necessary to establish the basis for determining the amount of Part B charges. For this, the first step is to ascertain the total amount the physician is to be paid by and through the hospital during the coming year under the arrangement as agreed by the parties. Where the physician's compensation is a percentage either of gross or net departmental income or figured on some other basis under which the amount of his compensation is not fixed in advance, the amount of total payments to the physician from and through the hospital can be properly estimated by adjusting the amount of payments to him for the previous year to take account of anticipated changes in the volume and character of the procedures to be performed and other factors that will affect income. Once the physician's total income from and through the hospital is ascertained, it is immaterial to the determination of the Part B charges whether the payment to him is made as a salary, as a percentage-of-gross income, or as payment from the hospital under some other arrangement.

(2) Next, any amounts that the physician may receive as reimbursement for costs he bears in furnishing supplies, employing personnel and meeting other expenses are to be subtracted from the amount of payments to him to ascertain the physician's compensation for his personal services for the year. The costs that are subtracted are reimbursable as hospital costs and not to be taken into account in determining the physician's Part B charge, as explained in principle 6 (Reg. Sec. 405.486).

(3) From the physician's compensation for his personal services, as derived in accordance with subparagraphs (1) and (2) of this paragraph, there must be subtracted compensation for the portion of the time the physician spends in the hospital performing research,

teaching, administration, and other activities which are not personal services to individual patients and which, therefore, do not meet the criteria prescribed in the first sentence of principle 3 (Reg. Sec. 405.483). To ascertain the amount of the physician's compensation for such services, it would be appropriate to consider the compensation for them to be paid in proportion to the time he devotes to them. For example, a finding that 15 percent of a physician's time in the hospital is spent in teaching, 30 percent performing administrative services, and 20 percent performing autopsies and other activities not identified as services to individual patients would indicate that the remaining 35 percent of his compensation for personal services is properly attributable to services for individual patients for which a Part B charge may be made when furnished to Part B beneficiaries. The amount so determined, while relating to Part B type services to all patients will nevertheless serve as the basis for establishing the amount of charges for physician's services to Part B beneficiaries in accordance with either of the procedures set forth, respectively, in paragraphs (b) and (d) of this section.

(b) *Determining the Part B charge for individual procedures under the item-by-item approach.* (1) Under the item-by-item approach described in principle 3 (Reg. Sec. 405.483), an evaluation must be made of each separate procedure or type of procedure to determine that part, if any, that is a service rendered in person by the physician to the individual patient for which a charge may be made under Part B. Principle 5 (Reg. Sec. 405.485) stipulates that in developing a schedule of Part B charges, the schedule must be developed in such a way as to yield an amount of charges which, in the aggregate, equals the physician's compensation for personal services to individual patients, the calculation of which is described in paragraph (a) (3) above.

One acceptable methodology for developing a schedule of itemized Part B charges complying with principles 5 and 8 (Reg. Secs. 405.485 and 405.488) is outlined below:

(i) Each procedure that involves a significant element of the physician's services to individual patients would be assigned a numerical value equal to the portion of the customary amount billed by the hospital for the procedure which recognizes such element in due measure. For example, if the customary charge for procedure X has been \$5 and one-half the charge expresses the portion that is for the physician's services

in person to individual patients when the procedure is performed, a numerical value of 2.5 (one-half of \$5.00) would be assigned to the procedure. A procedure that does not have a significant Part B component would not be assigned a numerical value.

(ii) The numerical value for each procedure is then multiplied by the number of times it is estimated that the procedure will be performed during the coming year. The amount of the physician's total compensation for Part B type services, as ascertained in accordance with paragraph (a) (3) above, is then divided by the sum of these products to yield the monetary value of each single unit of numerical value assigned to the respective procedures.

(iii) The monetary value of a single unit of numerical value is then multiplied by the numerical value that has been assigned to each procedure, and the product represents the Part B component—that is, the amount chargeable under Part B for the procedure.

An alternative methodology for arriving at a schedule of Part B charges for each such procedure (e.g., a biopsy or bone marrow study) would be to assign to each procedure a percentage of the physician compensation found, in accordance with paragraph (a), above, to be attributable to services to patients. The amount of compensation allocated in this manner to each procedure, when divided by the projected number of times the procedure is performed, would yield the amount of Part B charge for each such procedure included in the schedule.

Whatever methodology is used, rounding of the resulting amounts would be deemed appropriate under a consistent method designed not to affect significantly the aggregate amount of the Part B charges.

(2) The schedule of Part B charges so developed by the hospital and physician is to be submitted by the parties to the Part A intermediary and the Part B carrier together with data on the determination described in paragraph (a) (3) above and a brief description of the derivation of the schedule. In addition, the following information should be submitted for the procedures listed on the schedule:

(i) The estimated number of times the procedure will be performed in the hospital during the 12-month period for which the schedule is applicable. (Comparable data for a representative past period—e.g., a year—should also be submitted with an explanation of any significant deviations.)

(ii) The customary amount billed by the hospital for the procedure, inclusive of both Part B and Part A portions of the service involved in the procedure.

(c) *Approval of schedule of Part B charges determined on an item-by-item basis.* The Part B carrier would approve the schedule of Part B charges if it, with the advice of the Part A intermediary, concurred in the

physician's and hospital's determination under paragraph (a) (3) above concerning the portion of the physician's compensation for personal services in the coming year which is attributable to Part B type services and provided that such portion of compensation, plus, in cases where the physician bills directly, the portion attributable to costs of operation of the hospital department borne by him, if any (see principle 6 (Reg. Sec. 405.486)), approximates the sum of the products of (1) the number of the individual procedures, as described in paragraph (b) (2) (i), and (2) the Part B charges for each such procedure.

(d) *Computing the Part B component under the optional method.* (1) Where, because of the high volume of low-cost procedures or the lack of necessary statistical data, it would not be feasible for the physician and hospital to comply with the requirements of the item-by-item method, the optional method described in principle 3 (Reg. Sec. 405.483) would be applicable. The uniform percentage, described in principle 3 (Reg. Sec. 405.483), that is applied to the total charges for procedures for a medicare patient which involved the hospital-based physician's service is computed by dividing the physician's compensation for Part B type services, as ascertained in accordance with paragraph (a) (3) above, by the hospital's total billings for all such procedures to be rendered for patients in the coming year. This latter amount can properly be estimated by adjusting data on such billings for the previous year to take account of anticipated changes in the volume and of the procedures to be performed during the coming year and other factors that will affect the amount billed.

(2) The schedule of the customary amounts billed by the hospital for the procedure and the uniform percentage as computed will be submitted by the hospital and the physician to the Part A intermediary and the Part B carrier together with a brief description of the derivation of the uniform percentage. Explanation accompanying the submission should include:

(i) An estimate of the amount that would result from the application of the uniform percentage in the coming year if applied to the aggregate amount billed by the hospital for all procedures rendered by the department.

(ii) An estimate of the physician's compensation for Part B type services for the coming year (as described in paragraph (a) above).

(e) *Approval of schedule of Part B charges computed under the optional method.* The Part B carrier would approve the uniform percentage computed in accordance with paragraph (d) if it, with the advice of the Part A intermediary, concurred in the physician's and hospital's determinations under paragraphs (d) (2) (i) and (d) (2) (ii) and provided that the respective amounts so determined are not significantly different.





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PRINCIPLES OF REIMBURSEMENT FOR SERVICES BY HOSPITAL-BASED PHYSICIANS



U.S. DEPARTMENT OF
HEALTH, EDUCATION, AND WELFARE
SOCIAL SECURITY ADMINISTRATION
HIM-6

March 1967

Revision Transmittal No. 1

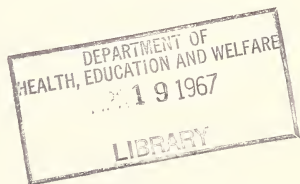
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Page 1 *Authority Last line: Change "CT Seq." to "et seq."

Page 3 *Authority Last line: Change "CT seq." to "et seq."

Page 4 Heading Change: (Reg. Sec. 405.480) to (Reg. Sec. 405.482)

Page 6 Heading Change: (Reg. Sec. 405.485) to (Reg. Sec. 405.484)







PRINCIPLES OF REIMBURSEMENT FOR SERVICES BY HOSPITAL-BASED PHYSICIANS

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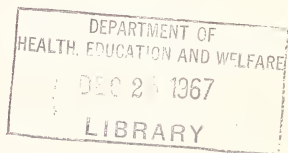
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HEALTH
INSURANCE
FOR THE AGED

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REIMBURSEMENT
FOR SERVICES BY
HOSPITAL-BASED
PHYSICIANS



U.S. DEPARTMENT OF
HEALTH, EDUCATION, AND WELFARE
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*AUTHORITY: 20 CFR 405, § 405.480-405.488 issued under secs. 1102, 1814(b), 1833(a), 1861(v), and 1871, 49 Stat. 647, as amended, 79 Stat. 296, 79 Stat. 322, 79 Stat. 331; 49 U.S.C. 1302, 1395 et seq.

U.S. Bureau of Health Insurance

REIMBURSEMENT FOR SERVICES BY HOSPITAL-BASED PHYSICIANS UNDER TITLE XVIII OF THE SOCIAL SECURITY ACT AS AMENDED (PUBLIC LAW 89-97)*

INTRODUCTION—(Reg. Sec. 405.480)

General. The Health Insurance for the Aged Act establishes two separate health insurance programs for the elderly. One provides hospital insurance protection to nearly all the aged financed largely through social security taxes. The other provides supplementary medical insurance to aged people who enroll and agree to pay monthly premiums, that are matched with amounts from Federal general revenues.

Sources of benefit payments. Under the law, benefit payments for the services of physicians (except for services of residents and interns under professionally-approved training programs) furnished to individual patients are under the supplementary medical insurance program. However, some of the services which hospital-based physicians perform are clearly not furnished to an individual patient. To the extent that the cost of such services is borne by the hospital, reimbursement will be made to the hospital under the hospital insurance program or, in certain cases, as a hospital cost under the supplementary medical insurance program.

Applicability of principles of reimbursement. The principles deal with the identification of the source and amount of benefit payments under the program for services performed by physicians (other than interns and residents) in a hospital setting under circumstances where physicians typically are salaried or receive compensation from or through the hospital under arrangements such that the physician is paid an agreed amount or the hospital remits to him an agreed portion of the collections from patients and the hospital collects the funds from patients either in its own right or as agent for the physician. These principles establish criteria for distinguishing between those services of physicians who are so compensated which are reimbursable to hospitals and such physicians' services to patients reimbursed under the supplementary medical insurance program. The principles also establish a basis for determining the reasonable charges for physicians' services to patients in situations where, under existing arrangements between hospitals

and physicians, billings to patients have not separately identified charges for physicians' services and charges for hospital services. (Where charges for physicians' services to patients have been identified separately from charges for hospital services, the customary charges for physicians' services thus will have been established and a basis afforded for determining the reasonable charges for such services. Where, for example, as is sometimes the case in the arrangements between hospital-based physicians and hospitals, especially, but not exclusively, in the arrangements between teaching hospitals and surgeons, among others, the charges for the physicians' services to the patient are separately identified, the determination of the reasonable charges for such services will take into account customary charges of such physicians so established.) Finally, the principles establish a basis for ascertaining the customary charges for a physician's services to patients in situations where, under the previously existing arrangement between the hospital and the physician, charges to patients had not been separately identified but where under a modification of the previously existing arrangement the hospital and the physician agree to bill patients separately for their respective services.

Arrangements for services of hospital-based physicians. Hospitals in the United States have in force a wide variety of arrangements for the compensation of hospital-based physicians. The Health Insurance for the Aged program does not require change in the substance of these arrangements, whether the arrangements call for compensation by way of salary, or a percentage, or in any other manner, or whether payments are received by the hospital (either in its own right or as agent for the physician) or are received directly by the physician.

In many cases, a physician contracts with a hospital to provide only his own professional services, the hospital assuming the cost of supporting personnel (who, in this case, are hospital employees) and bearing the expense of furnishing space, supplies, and the like. Sometimes, however, the physician assumes some or all of these costs. In some instances, the arrangement may constitute a concession or lease, the physician employing the supporting personnel and bearing all other

*Authority: 20 C.F.R. 405, 405.480-405.488 issued under secs. 1102, 1814(b), 1833(a), 1861(v) and 1871, 49 Stat. 647, as amended, 79 Stat. 296, 79 Stat. 322, 79 Stat. 331; 49 USC 1302, 1395 CT Seq.

expenses, including a payment to the hospital for the use of space.

Types of services rendered. Many hospitals retain physicians on a full-time basis as, for example, in the fields of pathology, psychiatry, anesthesiology, and radiology, and in many instances (especially in teaching hospitals) in other fields of medical specialization as well. The functions of these physicians vary widely. In some cases they devote full time to education or administration. Conversely, some are exclusively concerned with patient care. Any one of these physicians may be engaged in a variety of activities including teaching, research, administration, supervision of professional or technical personnel, service on hospital committees, and other hospital-wide activities, as well as direct personal health services to individual patients. Sometimes the hospital's arrangement is made with a group of physicians who assume joint responsibility for discharging agreed-upon duties.

Provisions for remuneration. The compensation to the physician generally is either on a salary basis, a percent of the gross income received from the patients for the particular services (usually a group of related services—all those performed in a radiology department, for example), or a percent of the net income (gross income less related expenses) received from patients, or some modification or combination of these (such as percentage with a guaranteed minimum). Generally the hospital collects the charges for the services of these physicians and their supporting personnel, acting in some cases in its own right, in some as agent for the physician. Where the arrangement between the hospital and the physician is that the compensation to the physician is on a salary or percentage of income basis, and the parties to the arrangement have thus agreed between themselves on the amount or the measure of compensation to be received by the physician for his services, the sum of the payments, with

respect to the physician's services, under both the hospital insurance program and the supplementary medical insurance program (including deductible and coinsurance amounts payable by beneficiaries) should approximate that portion of the agreed upon compensation which is attributable to covered services. Some hospitals, moreover, have arrangements with medical schools or other organizations under which physicians receive compensation from such organizations for services the physicians provide to hospital patients. The remuneration of physicians from such sources may be included in determining reasonable charges for physicians' services in accordance with principle 5 (Reg. Sec. 405.485).

Identification of types of services for purposes of program payments. However the billing is handled and whatever the method of distributing the proceeds between the hospital and the physician, it has been the almost universal practice to make a single charge to the patient for each of these services. In order to make payments under title XVIII of the Act, however, it is necessary where billing is by or through the hospital, to distinguish between the medical and surgical services rendered by a physician to a patient, on the one hand, and the hospital services (including physicians' services for the hospital), on the other. This is required because the payments will come from different trust funds, the payments will usually be handled by different intermediaries, and the methods of determining the two payments will differ materially. Thus, there are two sources of payment under the health insurance program for services furnished to beneficiaries covered under title XVIII of the Act. The hospital and the physician may, however, if they wish, pool the two payments where received by the hospital in its own right or as agent for the physician and may distribute the proceeds in accordance with their preexisting arrangement, or in any other way on which they may agree.

PRINCIPLES OF REIMBURSEMENT*

PRINCIPLE 1

Noninterference by Federal Government (Reg. Sec. 405.481)

It is not the function of the health insurance programs established under title XVIII of the Act to determine the arrangement which a hospital and a hospital-based physician may enter into for the compensation of the physician. The Secretary will not specify or influ-

ence the provisions of the contract or arrangement between hospitals and hospital-based physicians. The hospital and physician can continue to negotiate all aspects of their arrangement to their mutual satisfaction. These principles are designed to give recognition to the arrangement entered into by a hospital and a physician by establishing criteria for determining, within the framework of the arrangement, amounts payable under the hospital insurance program and amounts payable under the supplementary medical insurance program to the end that the total payments with respect to the physicians' services to the hospital and for the patient are related as closely as is possible to the level of compensation the parties have agreed upon.

*Authority: 20 C.F.R. 405, 405.480-405.488 issued under secs. 1102, 1814(b), 1833(a), 1861(v) and 1871, 49 Stat. 647, as amended, 79 Stat. 296, 79 Stat. 322, 79 Stat. 331; 49 USC 1302, 1395 CT seq.

PRINCIPLE 2

Program Payments for Physicians' Services to Hospitals and to Individual Patients (Reg. Sec. 405.480)

Principle. Whatever the arrangement may be between hospital and physician, the law requires that medical and surgical services rendered to a covered individual by a hospital-based physician be reimbursed only under the supplementary medical insurance program—Part B of title XVIII of the Act. The costs to a hospital for services furnished in a hospital by a physician which are not professional services to a patient are included in the reasonable cost reimbursement to the hospital.

Physicians' services to patients. Title XVIII of the Act specifically excludes from hospital cost reimbursement under Part A the cost of medical or surgical services provided by a physician, resident, or intern except for those services rendered by interns or residents in approved teaching programs. Therefore, compensation paid by the hospital to the hospital-based physician cannot be included in hospital reimbursable cost to the extent that it represents compensation for physicians' services described in Principle 3 (Reg. Sec. 405.483). Physicians' services, as defined in section 1861(q) of the Act, means "professional services performed by physicians, including surgery, consultation, and home, office and institutional calls * * *."

PRINCIPLE 3

Physician Service Under Part B (Reg. Sec. 405.483)

Principle. A professional service rendered by a physician to a hospital patient that can be reimbursed only under the supplementary medical insurance program (Part B of title XVIII of the Act), as distinguished from his professional services which are of benefit to patients generally, means an identifiable service requiring performance by a physician in person, which contributes to the diagnosis of the condition of the patient with respect to whom the charge under the supplementary medical insurance program is to be recognized, or contributes to the treatment of such patient.

Recordation and billing of charges on item-by-item basis. The component of the hospital-based physician's services for which reimbursement must be made under Part B of title XVIII of the Act, the supplementary medical insurance program, is only that part of his professional services with respect to which he is personally involved in the provision of services to individual patients as distinct from other professional services he may render in the hospital setting, such as teaching, research, performance of autopsies, committee work, quality control activities and administration. Compliance with this principle for various types of services rendered by hospital-based physicians normally will require:

(1) determination with respect to each separate service or type of service rendered, of what part may properly be charged under the supplementary medical insurance program,

(2) compilation of the results of these determinations in the form of a schedule either of amounts or percentages applicable to separate services or types of services, and

(3) recordation of such charges on an item-by-item basis for each service rendered to a patient.

Optional method of recordation and billing on a uniform-percentage basis. (1) Application of the item-by-item method may present special problems in the case of a particular hospital department. This is illustrated by pathology laboratory services and radiology services, which involve a high volume of individual procedures, variation in the extent of involvement in services on the part of technicians and others and on the part of the physician, and difficulty in distinguishing between professional activities which are of general benefit to all patients and those performed directly for an identifiable patient. Where the physician participates personally in some procedures and not in others by virtue of quality control activities or because his professional concern is directed to the result in a given case, it may be difficult to ascertain the presence or absence of a specific quantum of professional activity in an individual case. Moreover, the

assigning of the appropriate amount of "professional component" to a particular procedure or test for a particular patient receiving the benefit of the physician's service, as defined in this principle, may not only result in inequality of charges among patients but also may present an undue task of recordation. Administratively costly and impractical requirements could ensue in collecting the data needed for presentation of bills involving minimal charges on an item-by-item basis to individual patients. Under these conditions, it may not be administratively practical for the physician, the hospital and the Part B carrier to keep track of appropriate professional charges on an item-by-item and patient-by-patient basis.

(2) With respect to pathology services, for example, an individual entitled to Part B benefits under title XVIII of the Social Security Act (in connection with a hospital stay, or in connection with a series of outpatient diagnostic tests) will, on the average, have multiple laboratory procedures which in the aggregate permit the assumption that at some point with respect to at least some of the laboratory services there has been "an identifiable service requiring performance by a physician in person."

(3) In order to facilitate administration, provide a better cost control, and to assure a practical basis for handling charges to individual patients, an optional method of recordation and billing may be elected upon agreement by the physician and the hospital in appropriate cases. Under this optional method, the component of the physician's services to patients would be determined for all medicare patients through application of a uniform percentage to the total charges for such services in a particular department, with the percentage used being designed to produce in the aggregate a measurement of the professional component attributable to patient services which would not be significantly different in amount from that produced by the method of itemization of detailed measurement of such components reflecting variation in the factor of personal participation of the physician in each individual procedure for each individual patient. The percentage factor will be considered reasonable if it can be shown that it does not result from attributing as medical services to patients the costs of teaching, research, administration, and other services that are clearly reimbursable under the hospital insurance program.

(4) Election to use the optional method does not alter the applicability of the principles as the basic criterion for distinguishing professional services chargeable under the supplementary medical insurance program from those to be included in the hospital's reimbursable costs. The optional method is not available where it would result in a charge to medicare patients for services which are not ordinarily furnished by the physicians of the department of the hospital to hospital patients utilizing the services of that department.

PRINCIPLE 4

Hospital-Physician Agreements for Physician Compensation (Reg. Sec. 405.485)

Principle. For purposes of reimbursement, intermediaries and carriers will respect, within reasonable limits, an agreement between a hospital and a physician concerning the portion of the physician's compensation which, if he is engaged in the care of individual patients, is to be attributed to such care, and the portion which is to be attributed to service to the institution. The procedure hospitals and physicians are to follow in obtaining review of their agreement by intermediaries is described in principle 7 (Reg. Sec. 405.487). The amount attributed to the care of patients will, to the extent of services rendered to supplementary medical insurance beneficiaries (identified in accordance with principle 3 (Reg. Sec. 405.483)), be recognized as proper charges to such patients, reimbursable under the supplementary medical insurance program. The amount attributed to service to the institution will be recognized as a cost which is reimbursable to the hospital.

Scope and effect of agreement. Typically, contracts between hospital-based physicians and hospitals pro-

vide for the payment of an aggregate amount (in the form of a salary, a percentage arrangement, or on some other basis) to the physician for all of his services within the institution without a service-by-service itemization. Where the physician is on salary and normally spends full time in administration of departmental affairs, the full salary may be considered a reimbursable hospital cost item and medicare will bear its proportionate share of such cost. Where a salaried physician devotes only part of his time to institutional affairs and also renders an appreciable volume of personal patient care, only part of his salary may be attributed to hospital costs since the law requires that "medical or surgical services" must be excluded in determining a hospital's reimbursable costs.

Allocation of compensation by parties. An agreement by the parties that a certain portion of the physician's compensation will be excluded from hospital costs and will be charged to those patients who are identified in accordance with principle 3 (Reg. Sec. 405.483) will be respected unless, because of the small portion of time the physician devotes to the personal care of patients, such an agreement could lead to unreasonable charges to such patients.

PRINCIPLE 5

Schedules of charges for Part B physician's services (Reg. Sec. 405.485)

Principle. Once the portion of a physician's compensation attributable to professional services to supplementary medical insurance beneficiaries has been determined, a schedule of charges can be developed. To be deemed reasonable the charges should be designed to yield in the aggregate, as nearly as may be possible, an amount equal to such portion of his compensation. As among the patients to be charged (identified in accordance with Principle 3 (Reg. Sec. 405.483)), the allocation of charges may be based on a schedule of relative values, on a uniform percentage of the charges made by the hospital or the physician to other patients for both professional and supporting components of the services, or on another method approved by the carrier as equitable.

Development of schedules. Since the present almost universal practice does not separate the professional services to individual patients from the other components of hospital-based physicians' services for purposes of determining the manner or amount of his compensation, it is necessary to devise a method for making this separation. The approach set forth in this section starts with the assumption that the present level of compensation of hospital-based physicians is reasonable. The assumption, of course, is open to challenge in any given case, and the carriers must deal with such challenges on the basis of prevailing rates of compensation in comparable institutions.

Over a period of time the schedules of charges will be subject to revision in the light of changes in the prevailing levels of compensation.

Development of charges on per diem basis. Some relatively few hospitals in which the hospital-based physicians are compensated by salary or other fixed amount of remuneration do not charge on a fee-for-service basis for each service provided a patient, but charge a fixed, all-inclusive rate, computed on a daily or other time basis or a per-visit basis, applicable uniformly to each patient without regard to the quantum of service required by the patient and without distinction between hospital services and physicians' services. Psychiatric hospitals, tuberculosis hospitals, and some governmental general hospitals commonly follow such a charge practice. Other hospitals use the fixed charge method for all services or only in connection with the services of certain of their departments while charging on a fee-for-service basis for the various services actually furnished to the patients in other departments. Where the billing by the hospital is on a per diem or other time period basis or on a per-visit basis, charges for the professional services of hospital-based physicians to patients may be computed on such a basis for program purposes. Under this method, after the apportionment of the physicians' compensation has been made in accordance with Principle 4 (Reg. Sec. 405.484), a per diem, per visit, or other unit charge can be developed, designed to yield in the aggregate, as nearly as may be possible, an amount equal to the physicians' compensation attributable to professional services to patients.

PRINCIPLE 6

Effect of physician's assumption of operating costs (Reg. Sec. 405.486)

Principle. Where a hospital-based physician himself bears some or all of the costs of operation of a hospital department and bills his patients directly rather than through the hospital, the reasonable charges for his services recognized under the supplementary medical insurance program will reflect the costs so borne by him. Where all the costs are to be borne by the physician, charges heretofore established for such services by agreement between the physician and the hospital may be acceptable as reasonable charges for purposes of the supplementary medical insurance program, but they will require adjustment either upward or downward if the hospital has been bearing a cost significantly greater or less than its share of the proceeds of such charges.

Billing for physician services. (1) The objective in determining reasonable charges where the physician bills patients directly is the same as that expressed in principle 5 (Reg. Sec. 405.485); to bring about as little change as possible (in the normal case) in the compensation the physician receives for his services in the hospital. Where the physician bills the patient directly, costs of operating the hospital department which are borne by the physician will be reflected in his reasonable charges which are compensable under the supplementary medical insurance program; the hospital will receive reimbursement through the hospital insurance program for those costs, if any, which it incurs. Where, however, a hospital initially pays some or all of the operating expenses of a hospital department (e.g., pays the salaries of nonprofessional personnel and purchases supplies and equipment), even though subsequently those items and services for which it pays the operating expenses are furnished for the use of the physician in return for an agreed upon payment by the physician to the hospital, such operating costs are reimbursable under the hospital insurance program as hospital costs, and are not to be reflected in the reasonable charges of the physician. Any payments received by the hospital under such an arrangement shall be treated as a reduction of allowable costs of the hospital reimbursable through the hospital insurance program.

(2) Where a hospital has been receiving, as its portion of the receipts for such services, significantly more or less than the costs the hospital has incurred in the provision of the services, this excess or shortage should not be transferred from the hospital to the physician merely because he decides to bill his patients directly. Since payment to the hospital is made on the basis of its reasonable costs for all hospital services, the transfer of such excess or shortage to the physician necessarily would alter the total cost of patient hospital

and medical care—a result which the legislation was not intended to bring about. The reasonable charges of a physician who enters into a lease or similar arrangement with a hospital under which the physician assumes the costs of operating the department and bills the patients directly would be based upon the remuneration he received for his services immediately prior to the leasing arrangement plus his reasonable costs of operation, taking into account the hospital's cost experience in providing such services. Reasonable charges, so determined, would be subject to appropriate future adjustment to take into account changing economic factors. Reference back to the remuneration formerly received by the physician from the hospital as a factor in determining his reasonable charges under the lease or similar arrangement is required to give effect to the provisions of the statute which direct that consideration be given, in determining reasonable charges, to the customary charges generally made by the physician for similar services. Where no pattern of customary charges has been established for the physician's professional services to patients other than the compensation he received from the hospital for his services, such compensation would serve as the basis for establishing the customary charge.

(3) Since prevailing charges of physicians in the locality for similar services also are to be considered in determining reasonable charges of a physician, the charges of nonhospital laboratories, clinics, and the like for similar services would be taken into account in determining whether or not the customary charges, established in accordance with these principles, are within the range of prevailing charges. The situations, however, are frequently not comparable because of the large volume, and consequent low unit cost, of a laboratory that performs all of the services required in a hospital. Although charges prevailing in nonhospital laboratories are to be taken into account, they will not be guides for determining reasonable charges in situations where they would produce an unreasonable result.

(4) Although the law excludes physicians' services from the definition of hospital services, it further provides that services of nonphysicians aiding physicians are not deemed to be the services of a physician and are covered under the hospital insurance plan whether they are furnished by the hospital or by a physician under an arrangement with the hospital which calls for billing for such services to be by or through the hospital exclusively. Where, therefore, billing for services of a hospital department, including the services of the physician in such department, is by or through the hospital, the charges for the physician's services to the patient and for the nonphysician components of the services furnished by the physician under his arrangement with the hospital shall be determined as provided

in paragraph (1) of this principle, and may be included in a single bill which identifies separately the amounts billed for the respective components of the services. The amount of the physician's charge attributable to the nonphysician components of the service represents a cost to the hospital which is reimbursable to the hospital. The amount attributable to the physician's services to the patient is the physician's charge compensable under the supplementary medical insurance program.

(5) Also, tangentially related to the issue of billing for services of hospital-based physicians is the question of billing for diagnostic or therapeutic items or services not furnished in a hospital department, but under arrangements made by the hospital with outside

laboratories for such items or services. Many hospitals, especially smaller hospitals do not maintain full laboratory facilities. Such institutions frequently enter into arrangements with independent outside laboratories for the performance of diagnostic procedures, as, for example, in the field of pathology. In such instances, typically, the laboratory bills the hospital for the services performed, and the hospital, under present practices, bills the patient. Services performed under such an arrangement would be included as inpatient hospital services, and the cost thereof—that is, the cost the hospital incurs in paying the laboratory's charges for the services—would, if reasonable, be reimbursable to the hospital.

PRINCIPLE 7

Maintenance of records and review of reasonable costs and charges (Reg. Sec. 405.487)

Principle. Hospitals and hospital-based physicians will be required to keep records and furnish information to substantiate the agreements they enter into with respect to the allocation of the compensation of the physicians.

Rationale to support agreements for allocation of compensation. (1) Where the agreement between the hospital and the physician reasonably allocates the physician's compensation between services covered as costs to be reimbursed to the hospital and those covered under the supplementary medical insurance program on a charges basis, it will generally be accepted if the parties concerned furnish an acceptable rationale for the allocation.

(2) Such allocation (made in accordance with principle 4 (Reg. Sec. 405.484)) should be capable of substantiation by the hospital and the physician. The parties' determination and supporting information should be reviewed by the hospital insurance intermediary and the carrier. The intermediary will be responsible

for the approval of the portion of the physician's compensation which has been determined by the parties to be a cost which is reimbursable to the hospital and the carrier will be responsible for the approval or disapproval of the parties' reasonable charge determination.

(3) If the parties do not come to an agreement, or if either the hospital insurance intermediary or the carrier believes that the rationale does not justify the parties' allocation between reimbursable hospital costs and medical insurance charges, it will notify the other so that coordinated action, if necessary, can be undertaken. The fiscal intermediary responsible for hospital cost reimbursement and the carrier responsible for payments under the supplementary medical insurance program will resolve the issue by negotiation if possible, otherwise by time studies or other suitable methods.

(4) Under these principles, it is recognized that a physician who serves two or more hospitals may under his agreements have significantly different allocations and consequently significantly different charges for the same service in the different hospitals served by him.

PRINCIPLE 8

Effect of principles (Reg. Sec. 405.488)

Nothing in the foregoing principles restricts the right of the physician (in the absence of his acceptance of an assignment by the patient) to determine the amount of his charge to the patient for his services, or restricts the hospital and the physician in providing for such disposition of the payments received from the health insurance programs and the beneficiaries under the programs as they may agree upon.

The total costs of hospital and medical services to inpatients and outpatients prior to the inauguration of

this program should not be increased solely by reason of the requirement for division of payments for the services of hospital-based physicians between the hospital insurance program and the supplementary medical insurance program.

The foregoing principles will, to the extent they are applicable, also govern reimbursement in cases where physicians have a financial arrangement of the kind referred to in the Introduction (Reg. Sec. 405.480) under "Applicability of Principles of Reimbursement" with an extended care facility or home health agency and where a hospital-based physician provides services to the hospital's outpatients.



ILLUSTRATIVE METHODOLOGIES

The methodology is described in a setting in which there is a single physician in the hospital's pathology or radiology or other department. Where there is more than one physician in a particular department, the term "physician" should be read as "physicians," and where quantitative factors are stated or derived they should be combined for all such physicians.

(a) *Separating hospital payments to physicians into the Part A and Part B components as the basis for determining Part B charges.* (1) Whether the physician and hospital agree to utilize the item-by-item recordation and billing method or the optional method described in principle 3 (Reg. Sec. 405.483), it is necessary to establish the basis for determining the amount of Part B charges. For this, the first step is to ascertain the total amount the physician is to be paid by and through the hospital during the coming year under the arrangement as agreed by the parties. Where the physician's compensation is a percentage either of gross or net departmental income or figured on some other basis under which the amount of his compensation is not fixed in advance, the amount of total payments to the physician from and through the hospital can be properly estimated by adjusting the amount of payments to him for the previous year to take account of anticipated changes in the volume and character of the procedures to be performed and other factors that will affect income. Once the physician's total income from and through the hospital is ascertained, it is immaterial to the determination of the Part B charges whether the payment to him is made as a salary, as a percentage-of-gross income, or as payment from the hospital under some other arrangement.

(2) Next, any amounts that the physician may receive as reimbursement for costs he bears in furnishing supplies, employing personnel and meeting other expenses are to be subtracted from the amount of payments to him to ascertain the physician's compensation for his personal services for the year. The costs that are subtracted are reimbursable as hospital costs and not to be taken into account in determining the physician's Part B charge, as explained in principle 6 (Reg. Sec. 405.486).

(3) From the physician's compensation for his personal services, as derived in accordance with subparagraphs (1) and (2) of this paragraph, there must be subtracted compensation for the portion of the time the physician spends in the hospital performing research,

teaching, administration, and other activities which are not personal services to individual patients and which, therefore, do not meet the criteria prescribed in the first sentence of principle 3 (Reg. Sec. 405.483). To ascertain the amount of the physician's compensation for such services, it would be appropriate to consider the compensation for them to be paid in proportion to the time he devotes to them. For example, a finding that 15 percent of a physician's time in the hospital is spent in teaching, 30 percent performing administrative services, and 20 percent performing autopsies and other activities not identified as services to individual patients would indicate that the remaining 35 percent of his compensation for personal services is properly attributable to services for individual patients for which a Part B charge may be made when furnished to Part B beneficiaries. The amount so determined, while relating to Part B type services to all patients will nevertheless serve as the basis for establishing the amount of charges for physician's services to Part B beneficiaries in accordance with either of the procedures set forth, respectively, in paragraphs (b) and (d) of this section.

(b) *Determining the Part B charge for individual procedures under the item-by-item approach.* (1) Under the item-by-item approach described in principle 3 (Reg. Sec. 405.483), an evaluation must be made of each separate procedure or type of procedure to determine that part, if any, that is a service rendered in person by the physician to the individual patient for which a charge may be made under Part B. Principle 5 (Reg. Sec. 405.485) stipulates that in developing a schedule of Part B charges, the schedule must be developed in such a way as to yield an amount of charges which, in the aggregate, equals the physician's compensation for personal services to individual patients, the calculation of which is described in paragraph (a) (3) above.

One acceptable methodology for developing a schedule of itemized Part B charges complying with principles 5 and 8 (Reg. Secs. 405.485 and 405.488) is outlined below:

(i) Each procedure that involves a significant element of the physician's services to individual patients would be assigned a numerical value equal to the portion of the customary amount billed by the hospital for the procedure which recognizes such element in due measure. For example, if the customary charge for procedure X has been \$5 and one-half the charge expresses the portion that is for the physician's services

in person to individual patients when the procedure is performed, a numerical value of 2.5 (one-half of \$5.00) would be assigned to the procedure. A procedure that does not have a significant Part B component would not be assigned a numerical value.

(ii) The numerical value for each procedure is then multiplied by the number of times it is estimated that the procedure will be performed during the coming year. The amount of the physician's total compensation for Part B type services, as ascertained in accordance with paragraph (a) (3) above, is then divided by the sum of these products to yield the monetary value of each single unit of numerical value assigned to the respective procedures.

(iii) The monetary value of a single unit of numerical value is then multiplied by the numerical value that has been assigned to each procedure, and the product represents the Part B component—that is, the amount chargeable under Part B for the procedure.

An alternative methodology for arriving at a schedule of Part B charges for each such procedure (e.g., a biopsy or bone marrow study) would be to assign to each procedure a percentage of the physician compensation found, in accordance with paragraph (a), above, to be attributable to services to patients. The amount of compensation allocated in this manner to each procedure, when divided by the projected number of times the procedure is performed, would yield the amount of Part B charge for each such procedure included in the schedule.

Whatever methodology is used, rounding of the resulting amounts would be deemed appropriate under a consistent method designed not to affect significantly the aggregate amount of the Part B charges.

(2) The schedule of Part B charges so developed by the hospital and physician is to be submitted by the parties to the Part A intermediary and the Part B carrier together with data on the determination described in paragraph (a) (3) above and a brief description of the derivation of the schedule. In addition, the following information should be submitted for the procedures listed on the schedule:

(i) The estimated number of times the procedure will be performed in the hospital during the 12-month period for which the schedule is applicable. (Comparable data for a representative past period—e.g., a year—should also be submitted with an explanation of any significant deviations.)

(ii) The customary amount billed by the hospital for the procedure, inclusive of both Part B and Part A portions of the service involved in the procedure.

(c) *Approval of schedule of Part B charges determined on an item-by-item basis.* The Part B carrier would approve the schedule of Part B charges if it, with the advice of the Part A intermediary, concurred in the

physician's and hospital's determination under paragraph (a) (3) above concerning the portion of the physician's compensation for personal services in the coming year which is attributable to Part B type services and provided that such portion of compensation, plus, in cases where the physician bills directly, the portion attributable to costs of operation of the hospital department borne by him, if any (see principle 6 (Reg. Sec. 405.486)), approximates the sum of the products of (1) the number of the individual procedures, as described in paragraph (b) (2) (i), and (2) the Part B charges for each such procedure.

(d) *Computing the Part B component under the optional method.* (1) Where, because of the high volume of low-cost procedures or the lack of necessary statistical data, it would not be feasible for the physician and hospital to comply with the requirements of the item-by-item method, the optional method described in principle 3 (Reg. Sec. 405.483) would be applicable. The uniform percentage, described in principle 3 (Reg. Sec. 405.483), that is applied to the total charges for procedures for a medicare patient which involved the hospital-based physician's service is computed by dividing the physician's compensation for Part B type services, as ascertained in accordance with paragraph (a) (3) above, by the hospital's total billings for all such procedures to be rendered for patients in the coming year. This latter amount can properly be estimated by adjusting data on such billings for the previous year to take account of anticipated changes in the volume and of the procedures to be performed during the coming year and other factors that will affect the amount billed.

(2) The schedule of the customary amounts billed by the hospital for the procedure and the uniform percentage as computed will be submitted by the hospital and the physician to the Part A intermediary and the Part B carrier together with a brief description of the derivation of the uniform percentage. Explanation accompanying the submission should include:

(i) An estimate of the amount that would result from the application of the uniform percentage in the coming year if applied to the aggregate amount billed by the hospital for all procedures rendered by the department.

(ii) An estimate of the physician's compensation for Part B type services for the coming year (as described in paragraph (a) above).

(e) *Approval of schedule of Part B charges computed under the optional method.* The Part B carrier would approve the uniform percentage computed in accordance with paragraph (d) if it, with the advice of the Part A intermediary, concurred in the physician's and hospital's determinations under paragraphs (d) (2) (i) and (d) (2) (ii) and provided that the respective amounts so determined are not significantly different.











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